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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

DENIS MULLIGAN, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

IMPAX LABORATORIES, INC., LARRY HSU, and ARTHUR A. KOCH,

Defendants.

Case No. 3:13-cv-01037-EMC

CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Honorable Edward M. Chen

CLASS ACTION

DEMAND FOR JURY TRIAL

(Caption continued on next page)

HAVERHILL RETIREMENT SYSTEM, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. IMPAX LABORATORIES, INC., LARRY HSU, and ARTHUR A. KOCH, Defendants.	Case No. 3:13-CV-01566-EMC

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I. INTRODUCTION

1. Lead Plaintiff Boilermaker-Blacksmith National Pension Trust ("Lead Plaintiff") brings this proposed federal securities class action on behalf of itself and a proposed class of persons and entities who purchased or acquired Impax Laboratories, Inc.'s ("Impax" or the "Company") common stock during the period between June 6, 2011 and March 4, 2013, inclusive (the "Class Period") and were injured by virtue of the misconduct alleged herein (the "Class," defined more fully below). Lead Plaintiff seeks remedies under the Securities Exchange Act of 1934 (the "Exchange Act"). Defendants (as defined below) made a series of materially false and misleading statements and omissions of material facts during the Class Period which artificially inflated the value of Impax common stock. Later disclosures caused the price of Impax common stock to decline, causing injury to Lead Plaintiff and the Class.

2. Impax is a pharmaceutical company that engages in the development, manufacture, and marketing of bio-equivalent pharmaceutical products referred to as generics as well as branded products. Impax and certain of its former and current officers and directors issued false and misleading information to investors by failing to disclose pervasive, serious, and known deficiencies at Impax's manufacturing facility in Hayward, California, as well as Impax's inability to timely remedy these deficiencies as was required by the United States Food and Drug Administration ("FDA"). Accordingly, defendants lacked a reasonable basis for their repeated assurances to investors that Impax was capable of bringing its manufacturing and quality control systems into compliance with FDA standards so that a Warning Letter issued by the FDA in May 2011 to Impax could be resolved. Instead, in repeated statements, defendants touted their confidence their ability to resolve these issues, represented that many significant remedies had already been successfully implemented in response to the Warning Letter, and assured investors

that Impax was on track and had the capability to remedy deficiencies, all the while failing to disclose the truth about the pervasive and serious quality control and manufacturing deficiencies that existed at Impax for years before and then during the Class Period.

3. In particular, both prior to and throughout the Class Period, Impax and its senior executives were aware that persistent deficiencies existed both with regard to the Company's manufacturing facility in Hayward, California and also with respect to the Company's quality control procedures. Indeed, Impax was on notice of these serious problems directly from its regulator – the FDA. As early as 2009 and continuing through 2013, Impax was subject to FDA inspections and received notifications every year from the FDA detailing specific observations of non-compliance with important FDA regulations relating to good manufacturing procedures for the medications Impax was selling to the public. Impax endured this annual frequency of investigations and deficiency notices where the average drug manufacturing facility receives quality control inspections (*i.e.* Good Manufacturing Practice or "GMP" inspections) less frequently than once every two years. The notices Impax received contained detailed observations of the deficiencies cited by the FDA, and many of the observations were repeated year after year, including Impax's failure to properly investigate deviations in the manufacturing process that were likely indicators of failure to follow standards set for the manufacturing of pharmaceuticals designed to ensure, among other things, that medications in pill form are all of a uniform weight such that patients get the correct and safe dosage. Indeed, in certain of the formal FDA notifications the FDA expressly labeled its observations as "repeat observations", underscoring Impax's repeated inability to identify and remedy these conditions. These notices were of such importance that not only did the FDA expressly direct them to senior executives at Impax, including the Company's chief executive officer Larry Hsu, but FDA investigators

conducted several in-person close-out meetings in which they explained in detail to Larry Hsu and other executives the contents and potential consequences of these documents. Next, FDA investigators recorded their account of these meetings and conversations with executives in a consolidated report that was made available to Impax. Notably, when the FDA issued a notice to Impax in February 2013, that notice contained three "repeat observations" dating back to notices issued in 2011 and 2010 as well as the Warning Letter itself, meaning deficiencies that had been cited two and three years earlier had ***still*** not been corrected.

4. But defendants' knowledge of these problems – and Impax's repeated inability to remedy them – was not merely restricted to information provided by the FDA. Rather, Impax independently was aware of these conditions based on the observations and experiences of its own employees and outside consultants. Indeed, as set forth below through the detailed descriptions of multiple witnesses who were present at the Hayward manufacturing facility, Impax was well-aware that it had a long and continuous history of manufacturing and quality control deficiencies and an inability to cure them. For example, witnesses describe in detail that Impax lacked the proper facilities and procedures to ensure that materials remained sterile permitting, for example, insects to be present in the manufacturing facility; that its manufacturing machinery was out-of-date, leaked fluids, emitted "black specks" into tablets, and released metal shavings that found their way into medications; that its facilities were of inadequate size, causing materials and equipment to be moved from place to place and as a result risking contamination of medications; that critically important written records and documentation including operating procedures – which are essential for compliance with FDA standards – were not properly maintained; that important operating procedures were not only routinely violated but that the violations were tacitly tolerated; that Impax appointed supervisory staff ***even after*** those persons

demonstrated an inability to respect manufacturing standards or to accurately report in good faith problems in production; and that Impax lacked a corporate culture and commitment to successfully address the issues raised by the FDA.

5. In the face of these facts demonstrating both the severity and pervasiveness of the problems and Impax's repeated inability to meet FDA standards and to address the Warning Letter from the FDA, defendants nevertheless continuously assured the investing public of their "confidence" that these conditions could be promptly remedied; that Impax was "on track" to, and investors could be "comfortable" that Impax would, clear the Warning Letter problems by the target date of February 2012 (later moved back); that "significant" progress was being made to remedy these issues; and that Impax had successfully resolved issues previously identified as problems by the FDA when that was not the case. In short, investors were completely misled about the true state of affairs at Impax, its ability to fix its problems in a timely fashion and, ultimately, to satisfy the FDA such that Impax would no longer be subject to the Warning Letter and the serious implications the Warning Letter had for Impax's business. Indeed, defendants knew of or were deliberately reckless in ignoring the truth about the manufacturing and quality control deficiencies as well as Impax's repeated inability to remedy these issues.

6. On March 4, 2013, after nearly two years of assuring investors that Impax was capable of complying with the FDA's standards and was well on its way to doing so such that the Warning Letter would be cleared, Impax shocked the market when it disclosed that the FDA had completed inspection of the Hayward manufacturing facility and that, based on the inspection, the FDA cited twelve problems at the facility requiring remediation and memorialized in an FDA Form 483 (explained more fully below). Importantly, Impax also informed investors that the latest Form 483 identified three "repeat observations" – essentially deficient production practices

– that had been identified prior to the Warning letter, and thus had not been remedied in the two years' worth of Impax's improvement efforts, underscoring to the market that Impax had no capacity to cure its deficiencies and finally revealing to the market that defendants never had a basis to believe they were capable of clearing the Warning Letter. Impax further revealed that due to the manufacturing deficiencies, it did not expect to be able to launch Rytary – a drug for the treatment of Parkinson's disease – or a generic version of Concerta – a drug for the treatment of attention deficit disorder – until 2014. The market reacted immediately and severely to this disclosure with Impax common stock losing nearly 26% of its value in a single day on March 5, 2013, trading at a volume of over 11,696,547 shares – ***eighteen times*** (*i.e.* 1,800%) the average daily volume for the class period. Indeed, securities analysts who followed the Company were incredulous about how the Company could be in such a position based upon the prior disclosures from Impax. One analyst noted that Impax's failures seemed to be based on an inability to comply with "GMP (good manufacturing practices) 101" while another noted that these issues were "obviously indicative of some ***systemic issue***."

II. JURISDICTION AND VENUE

7. This Complaint sets forth claims under Sections 10(b), and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 ("Rule 10b-5"), against Impax, and Impax officers named as defendants herein, who were knowing or reckless participants in defrauding investors in connection with their material misrepresentations and omissions concerning FDA onsite inspections from 2011 through 2013 at Impax and the FDA's observations as noted in Form 483 the Agency issued in March 2012, as well as the Warning Letter the FDA issued to Impax in May 2011.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the 1934 Act (15 U.S.C. §78aa).

9. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa. Many of the acts and transactions that constitute the violations of law complained of herein, including the dissemination to the public of untrue statements of material facts, occurred in this District.

10. Impax maintains its principal executive offices at 30831 Huntwood Avenue, Hayward, California 94544. Certain of the acts and conduct complained of herein, including dissemination of materially false and misleading information to the investing public, occurred in this District.

11. In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

III. PARTIES

12. Lead Plaintiff is one of three Taft-Hartley trusts maintained by the Boilermaker National Funds. Lead Plaintiff is headquartered in Kansas City, Kansas and has over $7.7 billion in assets under management. Most of Boilermaker National Funds participants are union members affiliated with over 100 local lodges of The International Brotherhood of Boilermakers and who work in boiler construction or repair, ship building, forging, manufacturing and other industries. As set forth in Exhibits B and D, and incorporated here by reference, attached to the Declaration of Daniel S. Sommers in Support of Motion to Appoint Lead Plaintiff and Lead Counsel Boilermaker-Blacksmith National Pension Trust's Motion for Consolidation of Related

Actions, Appointment As Lead Plaintiff, And Approval of Selection Of Lead Counsel (Dkt. 15), Lead Plaintiff purchased Impax shares during the Class Period and suffered damage as a result of the securities violations alleged herein.

13. Defendant Impax is a publicly-traded company and was incorporated in the State of Delaware in 1995. The firm's corporate headquarters, research and development, and commercial manufacturing operations are located in Hayward, California. In California, the company utilizes a combination of owned and leased facilities mainly located in Hayward. Impax has two other facilities located in Philadelphia, Pennsylvania and Taiwan.

14. Impax, a specialty pharmaceutical company, engages in the development, manufacture, and marketing of bioequivalent pharmaceutical products. The Company operates in two divisions, Global Pharmaceuticals and Impax Pharmaceuticals. The Global Pharmaceuticals division develops, manufactures, sells, and distributes generic pharmaceutical products. This division provides its generic pharmaceutical prescription products directly to wholesalers and retail drug chains, and generic pharmaceutical over-the-counter and prescription products through unrelated third-party pharmaceutical entities, in addition to offering research and development services. The Impax Pharmaceutical division develops proprietary brand pharmaceutical products for the treatment of central nervous system disorders, including epilepsy, migraine, multiple sclerosis, Parkinson's disease, and restless leg syndrome, and promotes third-party branded pharmaceutical products. Impax markets and sells its generic pharmaceutical prescription drug products in the continental United States and the Commonwealth of Puerto Rico.

15. As part of its production process, Impax receives active pharmaceutical ingredients and raw materials used for the manufacturing of drug products through interstate commerce within the United States and also imports them. Once manufactured and released, the firm ships

bulk drug product from its Hayward, California facility to its packaging and labeling facility located in Philadelphia, Pennsylvania. Once packaged and labeled, the drug product is then sold to customers.

16. Impax has historically focused on generic drugs, which offer notably lower margins than branded drugs. In 2008, the Company launched its branded products division in an effort to diversify its revenue base. Rytary, also known as IPX066, is the first drug that Impax sought to take through the entire FDA approval process for new drugs.

17. Defendant Chungchiang Hsu, also known as Larry Hsu, ("Hsu") is, and at all relevant times was, the Company's Chief Executive Officer ("CEO"), President and a director. Hsu works in Impax's Hayward headquarters. During the Class Period, Hsu was designated by the FDA as "the most-responsible" person at Impax, and accordingly, important communications from the FDA to Impax were directed to him by the FDA. As described in Impax's June 25, 2013 press release, Hsu was "co-founder and later CEO…helped guide the Company from its founding in 1994, through the 1999 reverse merger with Global Pharmaceuticals that gave Impax its current shape." Hsu has been President and CEO since October 2006. Prior to holding these positions, Hsu served as President and Chief Operating Officer beginning in 1999. When Hsu co-founded Impax Pharmaceuticals, Inc. in 1994, he served as its President, Chief Operating Officer and a member of the board from its inception until its merger in 1999. From 1980 to 1995, Hsu worked at Abbott Laboratories, where, during his last four years, he served as Director of Product Development. Hsu's biography on the Impax website states further that Hsu's "experience as our co-founder, President and Chief Executive Officer, and previously our President and Chief Operating Officer, provides the board with unique insights into our operations, challenges and opportunities" and that he brings 30 years' experience to Impax's operations and business

strategies. During the Class Period Hsu received communications from the FDA – many of them addressed to, or personally hand delivered to him, by the FDA – and was otherwise informed about such communications including several Form 483s that detailed severe, pervasive, and repeated violations of well-known and longstanding FDA standards for good manufacturing practices, as well as a Warning Letter form the FDA which threatened severe regulatory action against Impax if the deficiencies were not timely addressed. Hsu frequently spoke publicly about Impax, its interactions with the FDA and the status of Impax's responses to problems identified by the FDA with respect to the Company's repeated failures to comply with good manufacturing practices. In particular, Hsu repeatedly spoke about these issues to securities analysts who regularly followed Impax, as well as in numerous Impax press releases. Hsu also signed Impax's filings with the SEC including Forms 10-K and 10-Q. In June 2013, Hsu and Impax announced that Hsu would be retiring as President and Chief Executive Officer of Impax.

18. Defendant Arthur A. Koch ("Koch") was, at all relevant times from April 2005 and until his resignation on June 29, 2012, Chief Financial Officer ("CFO") and Executive Vice President, Finance of Impax. Prior to joining Impax, he had been with Strategic Diagnostics Inc., a company that develops, manufactures and markets immunoassay-based diagnostic test kits, including six years as Chief Operating Officer, five months as interim CEO and five years as CFO and Vice President ("VP"). At Strategic Diagnostics, Koch's most recent responsibilities included responsibility for all profit and loss activities and leadership of the research, manufacturing and financial functions. He also was involved in several acquisitions and developed the company's investor relations campaign. Koch holds a Bachelor of Business Administration from Temple University and has been a Certified Public Accountant since 1977. Koch left Impax on June 29, 2012. Koch frequently spoke publicly about Impax, its interactions

with the FDA and the status of Impax's responses to problems identified by the FDA including to securities analysts who regularly followed Impax, as well as in numerous Impax press releases. Koch also signed Impax's filings with the SEC including Forms 10-K and 10-Q.

19. The defendants named above in ¶¶17-18 are referred to herein as the "Individual Defendants." The Individual Defendants along with Impax are sometimes referred to herein as "Defendants."

20. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Impax's quarterly reports, press releases, and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. They were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions with the Company, and their access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements they made as pleaded herein.

IV. WITNESSES

21. Lead Plaintiff, through counsel, conducted an investigation of the matters alleged in this Complaint, including through interviews of witnesses. As alleged and specified below, each witness worked at Impax, either as an employee, contract employee or consultant, and had experience with Impax's policies, practices, and methods of manufacture, storage, and quality control and quality assurance methods. Each and all of these witnesses was in a position to have

knowledge of the matters attributed to them by virtue of their particular job responsibilities as well as actual tasks performed in their positions as employees or contract employees of, or consultants for, Impax.

22. **Confidential Witness No. 1** ("CW 1"): CW 1 was a Manufacturing Technician II (the next level after the introductory level I) at Impax from 2006 until June 2013. Manufacturing technicians were the individuals who actually operated the machines on the manufacturing floor during production. As a Manufacturing Technician II, CW 1 was responsible for making medications using raw materials. CW 1 worked at the Hayward manufacturing facility. At the time CW 1 left Impax in 2013, CW 1 reported to Songwan Khachonritdet, who is a production supervisor. Prior to that time, CW 1 reported to Rod Guanzon after a period of employment during which CW 1 reported to Patrick Killenberg, a supervisor for the weighing and coating departments.

23. **Confidential Witness No. 2** ("CW 2"): CW 2 began working at Impax in December 2002, and was a Supervisor at Impax's Hayward manufacturing facility until April 2011. CW 2 supervised dayshift technicians during the course of their work on the manufacturing floor and CW 2 reported to Eric Baier (the Associate Director of Manufacturing) toward the end of CW 2's period of employment. In CW 2's capacity as supervisor, CW 2 reviewed production data to monitor department quality, productivity, and yields, investigated and wrote exception investigations on process, product, or procedural deviations, ensured execution of the manufacturing schedule and resolved any problems, reported to superiors on departmental performance, safety, employee training, and productivity metrics, oversaw the use of production equipment on the manufacturing floor and monitored the need for major cleans.

24. **Confidential Witness No. 3** ("CW 3"): CW 3 was a manufacturing engineer at Impax's Hayward manufacturing facility from August 2010 to October 2012. More specifically, from August 2010 until approximately March 2011, CW 3 was a Manufacturing Technician I, first as a contractor through a staffing company and then as a full-time employee. As a manufacturing technician, CW 3 handled and processed regulated materials, and worked in blending, milling, and screening. CW 3 worked the shift from 6 p.m. to 6:30 a.m. every Thursday, Friday, Saturday and every other Wednesday. CW 3 reported to Rob Guanzon, who was the compounding department shift supervisor and also reported to Robert Anderson, who oversaw the compounding department. From March 2011 until August 2011, CW 3 was a Production Engineering Associate and reported to Raymond Jahn (Director, Production Engineering). In that position, CW 3 learned how production engineering associates support manufacturing technicians. CW 3 managed procurement and production scheduling through purchase orders and report compilations for the Change Review Board, which CW 3 explained mostly consisted of Impax director-level employees and was designed to approve and oversee changes implemented in the manufacturing process. CW 3 was also responsible for implementing Standard Operating Procedures (SOPs). Finally, from August 2011 until October 2012, CW 3 was a Manufacturing Engineer and helped with Impax's "continuous improvement" manufacturing projects. As part of this program, CW 3 wrote new and updated existing SOPs in an effort to optimize equipment efficiency standards. In this position, CW 3 reported to Eric Baier (Assoc. Dir. of Manufacturing), Jeff Blumenfeld (Senior Director of Manufacturing) and then Alex Rodriguez when Rodriguez replaced Blumenfeld.

25. **Confidential Witness No. 4** ("CW 4"): CW 4 was a Manufacturing Technician I at Impax in its Hayward facility from February 2011 to January 2012. CW 4 has Bachelor of

Science degree in biology. CW 4 reported to the team lead, who reported directly to Supervisor Cindy Brashaun. CW 4 worked in the preliminary phase of manufacturing when compounds were weighed and sometimes mixed with other compounds, which included handling hazardous powder daily. In this capacity, CW 4 operated various manufacturing equipment used by Impax to manufacture product, including 5, 10, 30 cubic foot Gemco blenders, Fitsmill, ComMill, and a vibroscreen (sifter). CW 4 also worked on removing ambiguity from established SOPs.

26. **Confidential Witness No. 5** ("CW 5"): CW 5 was a Senior Manufacturing Supervisor from December 2002 until January 2012 at Impax's Hayward facility. CW 5 was responsible for supervising manufacturing technicians working the "graveyard" shift (the latest shift in the day that ran from before midnight until about 7 a.m.) and sometimes the night shift (which ran from 3 p.m. to 11:30 p.m.). CW 5 directed technicians and oversaw all aspects of manufacturing operations to facilitate compounding, tableting, encapsulation, and coating. CW 5 drafted work schedules and reviewed batch records, and was charged with maintaining compliance with FDA regulations.[1] CW 5 reported to Jeff Blumenfeld (Senior Director of Manufacturing).

27. **Confidential Witness No. 6** ("CW 6"): CW 6 was Associate Director of Manufacturing and Associate Plant Manager at Impax's Hayward facility from December 2008 until February 2012. CW 6 reported to Jeff Blumenfeld (Senior Director of Manufacturing). Daytime manufacturing supervisors reported to CW 6, and CW 6 was also responsible for training the personnel on all four shifts at the manufacturing facility.

[1] According to CW 5, technicians check-off their step-by-step execution of production steps on paper forms that are later compiled into "batch records." CW 5 stated that technicians also make notes on these checklists during the production process of any deviations from the steps required by SOPs. These production batch records are based off of a Master batch record (*i.e.* template) that is initially designed in the Research and Development (R&D) sector.

28. **Confidential Witness No. 7** ("CW 7"): CW 7 was a Quality Assurance Investigation Consultant at Impax's Hayward facility from August 2012 through October 2012. CW 7, along with one to two dozen other consultants from a consulting firm called Validant, worked at Impax in different departments to assist with various process improvements in an effort to address the FDA's observations. CW 7 often reported to Steve Fields, the Director of Analytical Sciences Brand in R&D at Impax, and who was the most senior Impax employee in the R&D building. (As a general matter, the R&D group researched and designed new drug formulas.) CW 7 worked directly with other Validant consultants at Impax's R&D building on issues that CW 7 understood had been cited by the FDA in its observations of the Quality Control group and that Impax had extended as improvement standards to its R&D group. As part of this mission, CW 7 reviewed all of Impax's lab data generated by R&D to identify compliance gaps, which included four of five years of data as compiled in R&D technicians' lab notebooks dating back to 2008. CW 7's task was to resolve data gaps by investigating the source. CW 7 and fellow colleagues working with CW 7 recorded their findings in two master Excel spreadsheets. Impax's Josie Castillo-Pascual (currently a Quality Assurance ("QA") Associate III in R&D) signed off on all of Validant's closed investigations. CW 7 learned that Steve Fields reviewed the spreadsheets and prepared summaries to present to his superiors.

29. **Confidential Witness No. 8** ("CW 8"): CW 8 was Director of Global Training from June 2010 until January 2013 at Impax. CW 8 worked in QA, which streamlined and standardized QA practices in all of Impax's locations. CW 8 also worked with contractors that Impax brought in to assist the Company with its quality improvements in response to FDA inspections. In particular, CW 8 was responsible for the development and management of technical and regulatory training, and integrated quality compliance systems for Impax. CW 8

worked on "solutions … large-scale efforts to build the quality system." CW 8 worked in several locations at Impax's Hayward facility, including the manufacturing sector for half a year, but spent most of CW 8's time in the primary executive building. CW 8 reported to Jeffrey Nornhold, whom Impax announced as the Senior Vice President of Quality Affairs in June 2011.

30. **Confidential Witness No. 9** ("CW 9"): CW 9 was a Senior Quality Assurance Compliance Associate at Impax from June 2010 to March 2013. CW 9 was involved in the assessment and implementation of remedial measures implemented after Impax received a Form 483 in April 2010. During the 2011 FDA inspection and resulting Form 483, CW 9 was the coordinator for gathering assembly documents and coordinating the subject matter of employees' specialties. As part of the FDA investigation, CW 9 coordinated Impax's "war room," which was located in Building 10 in the manufacturing building, where CW 9 was posted outside the conference room with a desk. Later, CW 9 performed the same tasks in trailers outside the manufacturing area. The "war room" was where CW 9 reviewed documents with colleagues before giving the documents to FDA investigators for review. FDA investigators then reviewed the documents in the "investigations room." CW 9 reported to John Osani, who was Senior Manager of Regulatory Compliance. After Osani left Impax in March 2011, CW 9 reported to Mark C. Shaw, who was Vice President of Regulatory Compliance. After Shaw left Impax in April 2012, CW 9 reported to Jeff Nornhold, Senior Vice President of Global Quality, until a replacement was found to manage compliance. In November 2011, CW 9 and colleagues in compliance were moved to the building on Genstar Road to work alongside Quality Assurance. Outside of tasks related to FDA inspections, CW 9 otherwise regularly conducted internal audits as well as audits of supplier companies.

31. **Confidential Witness No. 10** ("CW 10"): CW 10 was an Associate Director of Human Resources ("HR") at Impax from 2006 until August 2011. CW 10's responsibilities required that CW 10 oversee all functional aspects of HR management and services to the largest part of the corporation, the Operations Group which included Manufacturing, Project Engineering, FDA Validation Engineering, Production Engineering, Technology Transfer, Technical Services Manufacturing Support, Planning, Purchasing, SAP and ERP and Material Management. CW 10 conducted and/or lead Employee Relations investigations and participated in depositions. CW 10 regularly attended a weekly staff meeting in the conference room next to Hsu's office or in another conference room to the left of the office of David Huettig, who was Vice President of Engineering. Charles ("Chuck") Hildenbrand, Senior VP of Operations until he quit in June 2011, organized these weekly staff meetings. CW 10 attended the meetings with Jeff Blumenfeld (Senior Director of Manufacturing), Kangwen Lin (Director of Technical Services (Product Development)), Larry Glenn (Director of Operations in Philadelphia, attending by phone), Dave Huettig (VP of Engineering), and Joe Camargo (VP of Manufacturing & Materials Management/VP of Supply Chain). CW 10 also attended the monthly Continuous Improvement meetings that Hildenbrand held and that Hildenbrand had started in September 2007. Staff at these meetings included: Hildenbrand, May Chu (VP of Quality Assurance), Camargo, Huettig, Robert Bertolani (VP of Quality Systems Assurance), Jim Kou (Associate Director of Quality Control); Ray Jahn (Dir. of Maintenance Engineering), Lin, and Rosie Sison (Sr. Manager of Commercial QA).

32. **Confidential Witness No. 11** ("CW 11"): CW 11 was a Warehouse Supervisor at Impax from August 2009 until January 2013. CW 11 worked in Building 5, a large warehouse owned by Impax, and in a smaller warehouse located in Building 2, which was the manufacturing

facility. CW 11 traveled from Building 5 to Building 2 daily. For most of CW 11's employment, CW 11 shift was from 10 a.m. until 10 p.m. Within the last year of CW 11's employment, the company changed from 4 to 3 shifts and CW 11 took over the swing (overnight) shifts. CW 11 reported to Ron Valine, CW 11's supervisor, who in turn reported to Camargo (VP of Manufacturing & Materials Management/VP of Supply Chain).

33. **Confidential Witness No. 12** ("CW 12"): CW 12 worked at Impax from 2006 to May 2012. From 2006 to May 2009, CW 12 was a Manufacturing Technician at Impax and was responsible for maintaining compression equipment at the Hayward manufacturing facility. CW 12 was a manufacturing facility Tooling Specialist from 2009 to May 2012 on the night shift (6 p.m. to 6 a.m.) and was responsible for all equipment on the manufacturing floor, as well as ordering new tooling and maintaining tooling inventory. CW 12 reported directly to Pierre Dubois, who was a supervisor. Dubois reported to Raymond Jahn, who was Director of Production Engineering. CW 12 described CW 12's position as, essentially, "I was a shop store: I issued equipment and tools, cleaned equipment." CW 12 was centrally located but also had to move equipment to different areas, and check to make sure that people had the equipment they needed. The tool room that CW 12 ran was the place for employees to obtain necessary and common equipment such safety breathers, so every employee passed by at some point during the shift. As such, CW 12 observed many things first-hand, but also heard "all the complaints from employees as they came by" CW 12's shop.

34. **Confidential Witness No. 13** ("CW 13"): CW 13 was a Maintenance Manager at Impax from 2008 to May 2011 and worked in the company's Hayward manufacturing facility. CW 13 reported to Raymond Jahn, who, in turn, reported to David Huettig, Director of Engineering. CW 13's job was to maintain the mechanical integrity of the manufacturing

machines. CW 13 was explicitly named in the FDA 2011 narrative about its inspections (called an "EIR" and explained below) as an interviewee. At the time of that January 2011 report, CW 13 had been employed with Impax approximately two years. CW 13's responsibilities included the supervision of maintenance technicians and the approval of completed maintenance work orders. CW 13 provided information to the FDA investigators regarding routine and non-routine maintenance work orders, and equipment technical information.

V. THE FDA INSPECTION PROCESS

A. THE PURPOSE OF INSPECTIONS

35. The FDA's purpose in inspecting facilities for compliance is to "[p]rotect[] consumers and enhanc[e] public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products." *See Inspections, Compliance, Enforcement, and Criminal Investigations* (Dec. 16, 2011), *available at* http://www.fda.gov/ICECI/Inspections/IOM/ ucm124442.htm (last updated Sept. 4, 2013). The FDA conducts inspections of establishments that manufacture, process, pack, or hold FDA-regulated products, before approving products and/or after products are on the market, to determine the establishment's compliance with laws administered by FDA. *About FDA - Inspections*, http://www.fda.gov/AboutFDA/Transparency/PublicDisclosure/DraftProposalbyTopicArea/ucm211861.htm (last updated May 20, 2010). "An establishment inspection is a careful, critical, official examination of a facility to determine its compliance with laws administered by FDA." *FDA Investigations Operations Manual* 5.1.2 (2012), http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf ("Operations Manual") (the 2012 operations manual is the most recent manual on the FDA website).

36. During inspections of manufacturing facilities like those at Impax, the FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with the FDA's Current Good Manufacturing Practice ("cGMP") regulations. cGMPs are not aspirational or model policies: according to the FDA, "the cGMP regulations for drugs contain ***minimum requirements*** for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product." *Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm (last updated Sept. 7, 2012) (emphasis added). *See also Facts About Current Good Manufacturing Practices (cGMPs)*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ ucm169105.htm (last updated May 2, 2013) ("It is important to note that cGMPs are ***minimum requirements***.") (emphasis added). cGMPs make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. *Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations*, *supra*. Many elements of production are targeted in cGMPs, and not just a company's practices, protocol, and records, but also the equipment itself in the facility. For instance, the FDA acknowledges that part of cGMP compliance can require replacing machinery, despite its mint condition: "Systems and equipment that may have been 'top-of-the-line' to prevent contamination, mix-ups, and errors 10 or 20 years ago may be less than adequate by today's standards." *Facts About Current Good Manufacturing Practices (cGMPs), supra.* Finally, "[f]ailure to comply [with cGMPs] can also lead to a decision by FDA not to approve an application to market a drug" since the "FDA cannot approve applications to market new drugs from companies who have been cited for Current Good Manufacturing Practice violations." *Id.*

B. THE FREQUENCY OF INSPECTIONS

37. The Food, Drug & Cosmetic Act, Title 21 of the U.S. Code, requires the FDA to inspect manufacturing facilities at least once every two years. 21 U.S.C. § 360(h); 21 CFR § 312. These are called GMP inspections. (cGMPs along with "Quality System" regulations are, together, called "GMP Regulations." Jonathan Berman, *Current Trends in FDA's Enforcement of GMP Requirements* (Mar. 2013), *available at* http://www.lexology.com/library/detail.aspx?g=046878c8-7e97-408c-8467-869d34bd566d (last visited Sept. 10, 2013). However, due to the drastically increasing number of businesses in the market place, the FDA acknowledged within the last decade that the "Agency no longer has the resources to meet this statutory requirement" that every facility will be inspected within two years, and as such, cannot execute "uniformly intensive cGMP inspectional coverage." FDA, *Risk-Based Method for Prioritizing cGMP Inspections of Pharmaceutical Manufacturing Sites – A Pilot Risk Ranking Model* 3-4 (Sept. 2004), *available at* http://www.fda.gov/ohrms/dockets/ac/04/briefing/2004-4080b1_04_risk-based.pdf (last visited Sept. 10, 2013). In response, and beginning in fiscal year 2005, the FDA implemented a risk-based model for prioritizing the inspection of certain facilities above others. *Id.* As part of this program, the FDA focused on three categories of facilities for high priority: (1) those that produce sterile drug products, (2) those that produce other (non-gas) prescription drugs, and (3) new registrants that had not been inspected previously. *Id.* at 4.

38. By January 2009, the Government Accountability Office (the "GAO") added the FDA to its high-risk list of agencies that are under-resourced or under-performing due to a vastly growing number of businesses in the marketplace that are required to be overseen by the FDA. GAO, *High Risk Series: An Update* 115, No. GAO-11-278 (Feb. 2011), *available at* http://www.gao.gov/new.items/d11278.pdf (last visited on Sept. 10, 2013). The FDA remained

on the GAO's watch list, and the GAO found again in 2011 that the "FDA has been unable to fulfill some of its statutory requirements, such as biennially inspecting certain manufacturing establishments." *Id.* Thus by 2011, the FDA has still been unequipped to inspect all facilities by the statutory deadline – meaning the average inspection rate of all drug manufacturing facilities is less than once every two years. Thus the gap between the number of operating drug manufacturers and the FDA's "cGMP inspectional coverage" that the FDA cited in 2004 has persisted.

39. Nonetheless, the FDA has managed in recent years to conduct about 1,500 GMP inspections a year at drug and biologics manufacturers. ("Biologics" refer to manufacturers that produce blood-based products.) In FY 2011, out of 1,512 domestic GMP inspections, the FDA issued only 52 Warning Letters. Joanne S. Eglovitch, *The Gold Sheet* 47:3 (Mar. 2013), http://www.xavierpharmalink.com/wp-content/uploads/2010/08/Gold_Issuing40DrugGMPWarningLetters.pdf (last visited on Sept. 10, 2013). In FY 2012, the FDA issued only 40 Warning Letters among its 1,447 domestic GMP inspections. *Id.*

C. THE METHOD OF INSPECTIONS

40. FDA investigators may or may not give notice prior to arriving onsite at a drug manufacturing facility to conduct an inspection. Operations Manual 5.2.1.1. When FDA staff perform an investigation, they arrive onsite and begin by handing a Form 482 Notice of Inspection "to the top management official" on the first day of the inspection. Operations Manual 5.1.1.3. A Form 482 states the basis for the FDA's authority to conduct an investigation. At all times that investigators roam the facilities, they are accompanied by the investigated company's staff.

41. At or near the very beginning of the inspection, the investigators conduct a visual tour of the facility to familiarize themselves with the premises and staff. Operations Manual 5.1.2.2. The team leader of the group of FDA investigators will have designed, pre-inspection, a plan for the investigation that includes the areas to be observed, division of tasks, daily goals, and that ensures early understanding among all FDA team members of their roles in taking notes and generating documentation. *Id.* at 5.1.2.5.2.

42. The "FDA inspects pharmaceutical manufacturing facilities worldwide using scientifically and cGMP-trained individuals whose job it is to evaluate whether the company is following the cGMP regulations." *Facts About Current Good Manufacturing Practices (cGMPs)*, *supra* (emphasis added). Trained investigators tour facilities, accompanied at all times by the inspected company's staff, and "cite factual observations of significant deviations from the FD&C Act [21 U.S.C. 301], PHS Act, 21 CFR, and other acts where FDA has enforcement authority." Operations Manual 5.2.3.2. Investigators note facts that, in their judgment, constitute violations of FDA standards. *Id.* at 5.2.3. These findings are recorded in a concise Form 483 (explained below), which is presented and thoroughly explained to management on the last day of inspection. Prior to presentation of the Form 483 on the last day, investigators and analysts are instructed to "make every reasonable effort to discuss all observations with the management of the establishment as they are observed or on a daily basis, to minimize surprises, errors, and misunderstandings when the FDA [Form] 483 is issued" at the end of the inspection process. *Id.*

43. After the issuance of a Form 483, investigators write what is called an Establishment Inspection Report (an "EIR"), and the inspected company can request a copy of the EIR within 30 to 60 days. An EIR details inspectional findings and contains a narrative about conversations that investigators had with individual employees, management, and executive

management. An EIR contains more detail than a Form 483, and also may contain objectionable conditions not detailed in the Form 483. The narrative section of an EIR details what was covered during the inspection. The objectionable findings/conditions section of an EIR includes a detailed account of each objectionable condition (verbal and/or listed on the FDA 483) including a clear description of each, its impact on the product, batches or lots involved, and any relationship to other products or processes. Investigators will identify in the EIR the responsible party for each violation. The EIR will also include any discussion of all objectionable conditions from the daily inspection review and the discussion with management at the conclusion of the inspection. Accordingly, an EIR will include a "Discussion with Management" section of the report that records management's response to objectionable conditions which are discussed during the exit interview. It also includes the names and titles of each person at the exit interview. From the Form 483 and the EIR, additional reviewers at the FDA will make a formal finding of whether the company has violated any regulations and, if so, what further action is appropriate.

D. CATALOGUING AND COMMUNICATING OBSERVATIONS OF NONCOMPLIANCE TO THE REGULATED ENTITY AND ITS SENIOR MANAGEMENT

44. If objectionable conditions are observed during the inspection, investigators provide the owner of the establishment with a document, called an FDA Form 483, on the last day of the inspection. The purpose of the FDA Form 483 is to "notif[y] the company's management of objectionable conditions." FDA, *Form 483 FAQs*, http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm (last updated Mar. 13, 2012). (In certain instances of voluminous observations or documentation, a Form 483 may be presented later, but the FDA strongly discourages this practice. Operations Manual 5.2.3.1.) A Form 483 "is intended for use in notifying the inspected establishment's top management in writing of ***significant objectionable***

conditions, relating to products and/or processes, or other violations of the FD&C Act and related Acts [] which were observed during the inspection." *Id.* 5.2.3 (emphasis added); *id.* at 5.2.3.1 (Normal protocol states that Form 483 "should be issued at the conclusion of the inspection and prior to leaving the premises."). The FDA instructs its investigators that all observations recorded in a Form 483 "should be significant and correlate to regulated products or processes being inspected" and that the "observations should be ranked in order of significance" as listed on the form. *Id.* at 5.2.3. (These same standards were part of the FDA Operations Manual for 2011, dated December 2010. *See* 2011 Investigations Operations Manual 5.2.3 (December 10, 2010)). Investigators are instructed that "[o]bservations of questionable significance should not be listed on the FDA-483, but will be discussed with the firm's management so that they understand how uncorrected problems could become a violation. This discussion will be detailed in the EIR." *Id.* at 5.2.3. Investigators may note whether an observation is recurring or not corrected (*i.e.* a "repeat observation"), but this notation is not required. *Id.*

45. At the end of the inspection process, FDA investigators must present a hard copy of the Form 483 to the highest-ranked "owner, operator or agent in charge." *Id.* at 5.2.3.6.1. The Operations Manual requires that "[a]fter completion of the inspection," investigators "meet with the highest ranking management official possible to discuss [the FDA agent's] findings and observations. The FDA [Form] 483 is not a substitute for such discussion since there may be additional questionable practices or areas not appropriate for listing on this form." *Id.* at 5.2.7. Agents must discuss separately each observation listed on the Form 483 and explain that the observations are of:

> objectionable conditions found during the inspection, [while] explain[ing] the significance of each …. [and trying] to relate each listed condition to the applicable sections of the laws and regulations administered by the FDA. [Agents should] inform management during the closeout discussion the conditions listed

> may, after further review by the Agency, be considered to be violations of the Food, Drug and Cosmetic Act or other statutes. Legal sanctions available to FDA may include seizure, injunction, civil money penalties and prosecution, if establishments do not voluntarily correct serious conditions.

Id.

46. Management has fifteen days to provide written responses to the Form 483 observations; and a company's response may affect the FDA's final determination of subsequent action. *Id.* Where responses to a Form 483 are found to be inadequate, the FDA may issue a Warning Letter. During FY 2012, the average amount of time the FDA took to issue a warning letter was about 6.56 months after the issuance of a Form 483. *The Gold Sheet* 47:3.

E. WARNING LETTERS

47. The FDA defines a Warning Letter as:

> A Warning Letter is a correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations. Typically, a Warning Letter notifies a responsible individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations and other federal statutes. ***Warning Letters should only be issued for violations of regulatory significance, i.e., those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected***. A Warning Letter is one of the Agency's principal means of achieving prompt voluntary compliance with the Act.

FDA, *Regulatory Procedures Manual* 4.1 (July 2012) (emphasis added), *available at* http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM176965.pdf (last visited Sept. 10, 2013). Prior to issuing a Warning Letter, the FDA considers several factors, including: (1) "The firm's compliance history, *e.g.*, a history of serious violations, or failure to prevent the recurrence of violations;" (2) "The nature of the violation, *e.g.*, a violation that the firm was aware of (was evident or discovered) but failed to correct;" and (3) "The overall adequacy of the firm's corrective action and whether the corrective action

addresses the specific violations…." *Id.* at 4-1-3. Most importantly, the FDA's policy requires that "a Warning Letter should not be issued if the agency concludes that a firm's corrective actions are adequate and that the violations that would have supported the letter have been corrected." *Inspections, Compliance, Enforcement, and Criminal Investigations, supra*, at 4-1-1, http://www.fda.gov/ICECI/ComplianceManuals/ RegulatoryProceduresManual/ucm176870.htm

48. Whether the problems giving rise to a Warning Letter have been solved is decided by the FDA district office after the next onsite inspection, the timing of which the FDA decides. *Id.* Warning Letters are fully resolved when the FDA issues a "Warning Letter close-out letter" which "will not be issued based on representations that some action will or has been taken. The corrective actions must actually have been made and verified by FDA." *Id.* at 4-1-8. The FDA's policy is that district offices "should issue close-out letters within a total of 65 working days of having the necessary information upon which to make a decision." *Id.*

VI. IMPAX HAD A HISTORY OF REPEATED OBJECTIONABLE CONDITIONS IN VIOLATION OF GMP REGULATIONS

49. Defendants were well aware that Impax received a series of notifications from the FDA highlighting significant deficiencies in its cGMP practices and other areas of quality control year after year, leading up to the Form 483 issued by the FDA in 2013. The FDA issued Form 483s to Impax in 2009, 2010, 2011, 2012 and 2013. In 2011, chronic deficiencies provided the basis for the FDA to issue a Warning Letter – a document that constitutes official agency action and that can forestall the approval of any pending drug applications. Thus, with each subsequent year since at least 2009, Impax and the Individual Defendants were on notice of numerous problematic deficiencies that the FDA's trained and experienced compliance investigators believed to be significant cGMP deficiencies. Despite the various remedial measures Impax

attempted or did implement, Defendants were well-aware that Impax continued to fail to meet FDA standards time and time again.

50. As detailed below, the problems identified by the FDA and Impax's inability to remedy them all had consistent themes and repeatedly demonstrated to Defendants that Impax lacked the capacity to successfully addresses these issues.

A. THE FORM 483s FROM ALL FIVE YEARS REPEATED THE SAME cGMP DEFICIENCY

51. Most notably, all Form 483s spanning five years as well as the Warning Letter cited Impax for a failure to thoroughly investigate and document the investigation of deviations in manufacturing – the bedrock of an ability to adapt and maintain Quality Control ("QC"). As a general matter, deviations in manufacturing may indicate that the quality of a final product is unacceptable, and also could affect or even preclude release of the product for sale. As such, cGMP practices require that Impax employees investigate and document a deviation for the "root cause," and, where appropriate, investigate the extent of the deviation's impact on product quality. This investigation and documentation of it are vital to the success of remedial measures (*e.g.* new employee training, equipment repair, or updated SOPs, among other remedies), which, in turn, reduce the likelihood of the deviation's recurrence. Indeed, as FDA investigator Baker explained to Rob Bertolani (VP of Quality Systems Assurance) during the 2011 FDA inspection and as memorialized in the EIR, "during the manufacturing process, ***it is critical*** to perform thorough product investigations when deviations are identified." (Emphasis added.)

52. With regard to this protocol, and along with some factual variations about the many different instances in which Impax failed to adhere, the FDA consistently cited Impax each year for failure to perform full investigations in accordance with cGMPs. Indeed, the FDA formally labeled these ongoing failures as a "repeat observation" in three notices, first in the 2010

Form 483 and as repeated in (1) the 2011 Form 483, (2) the 2011 Warning Letter, and (3) the 2013 Form 483. Nonetheless, failure to fully investigate deviations was a consistent and continuous deficiency cited ***each year*** from 2009 to 2013. The trend included:

(a) ***failure to document the probable root cause*** for product erroneously packaged without desiccant on two occasions or to document the probable root cause related to that deviation's impact on product quality (2009 Form 483, emphasis added);

(b) "***failure to thoroughly review any unexplained discrepancy*** whether or not the batch has already been distributed" and a failure to address the root cause in the investigation of metal contamination (2010 Form 483, emphasis added);

(c) "***failure to thoroughly review any unexplained discrepancy*** whether or not the batch has already been distributed" as exhibited by: (1) corrective measures that failed to cure metal contamination or eradicate "black specks" in various products, (2) failure to assess the impact on the quality of a product made with the wrong ingredient, (3) failure to investigate the root cause of a pungent odor in a product that caused consumer complaints, and (4) failure to investigate the suitability of capsules that were below weight (2011 Form 483, emphasis added);

(d) ***"not thoroughly investigat[ing] the failure of a batch or any of its components to meet its specifications***, whether or not the batch has already been distributed" as exhibited by continued metal contamination problems (2011 Warning Letter, emphasis added);

(e) "***failure to document and investigate unexplained discrepancies*** that arise during the course of manufacturing and QC analytical testing" (2012 Form 483, emphasis added); and

(f) "***failure to thoroughly review any unexplained discrepancy***" in the "specifications" of a "batch or any of components" as exhibited by (1) a failure to investigate the root cause of deviations in rinse water, (2) failure to identify the root cause of a "known occurrence" of broken tablets in batches of a product, and (3) failure to address the impact of humid storage conditions on a product ingredient (2013 Form 483, emphasis added).

B. THE 2013 FORM 483 CITED TWO ADDITIONAL "REPEAT OBSERVATIONS" THAT HAD REMAINED UNCORRECTED FOR TWO YEARS

53. In addition to the repeated cGMP deficiencies, above, the 2013 Form 483 noted two more formally-labeled "repeat observations" dating back to the 2011 Form 483. The 2013

Form 483 stated that (1) "Written procedures are not followed for evaluations done at least annually" that included "provisions for review" of complaints, recalls, and investigations into them, and (2) that "[c]ontrol procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability" in production (*i.e.* there were no control procedures justifying the choice of certain manufacturing standards). Each of these "repeat observations" was supported by various examples that FDA investigators observed, while the ***same*** Observations in the 2011 Form 483 (that gave rise to the FDA indication of "repeat observations" two years later in the 2013 Form 483) also had several different examples supporting the Observation. Thus the 2013 Form 483 not only confirmed continued failure to observe proper cGMP practices, but also that three specific deficiencies were chronic and had remained unresolved since ***before*** the FDA's Warning Letter.

54. The Observations cited in the Form 483s issued during the Class Period (years 2011, 2012, and 2013) detailed a total of 22 Observations, including three formally designated as "repeat observations" in the 2013 Form 483, one of which had also been formally designated as a "repeat observation" in the 2011 Form 483 and the Warning Letter. Together, these deficiencies described numerous quality control problems in various situations, some uncorrected for at least three years. The frequency and number of Observations during the Class Period – in a market where the average FDA inspection was less than once every two years – underscored Impax's chronic inability to manage pervasive shortcomings in cGMP, regulations that the FDA deems "***minimum requirements***." *See Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations*, *supra* (emphasis added).

C. THE 2009 FORM 483

55. Investigators Sharon K. Thomas and Lance M. De Souza authored the 2009 Form 483 after an onsite inspection from July 27 to August 7, 2009, and presented it to Mark Shaw, VP of Regulatory Affairs & Compliance. The Form 483 enumerated ***four*** Observations, supported by observations of nine specific events. The four categories were: (1) the quality system, for failure to investigate root causes of out of specification ("OOS") events; (2) facilities and equipment, for failure to validate (*e.g.* investigate and justify) standards Impax set for cleaning; (3) laboratory systems, for failure to update weight calibration and for three instances of failure to note in data notebooks that certain retesting samples emanated from a particular sample that failed; and (4) production systems, for failure to stop operations and investigate when product powder "was flowing in a steady stream" outside of the plastic enclosure on a piece of equipment.

56. As noted above, the 2009 Form 483 cited a deficiency that would also reappear in several separate instances in all ***five*** Form 483s that the FDA issued to Impax in 2009, 2010, 2011, 2012 and 2013: its ***consistent and pervasive failure to fully investigate products that did not meet specifications***. Here, the supporting explanation that investigators cited was that "[t]here was no explanation written concerning probable root cause related to integrity of coating" and also inadequate records for "investigational follow-up" for a product that was initially and erroneously packaged without the required desiccant on two occasions.

D. THE 2010 FORM 483

57. Six months later, Impax received a Form 483, presented to Mark Shaw and due to "[s]ignficant cGMP deficiencies" (as stated in the resultant EIR) that FDA investigators, Peter E. Baker, Kevin P. Foley, Andrei Periloni, had observed during an inspection from April 7, 2010 through April 22, 2010. The 2010 Form 483 contained ***seven*** Observations covering nine events

related to manufacturing standards and review of manufacturing, which, more specifically, were grouped into deficiencies observed in (1) SOPs, for scientifically unsupported cleaning procedures and deficiencies in completeness; (2) test methods, for failure to establish the sensitivity and accuracy of QC testing methods; and (3) lack of review of deviations with regard to metal contamination in product.

58. In particular, Observation 6 echoed the familiar "failure to thoroughly review any unexplained discrepancy." As an example of this deficiency, FDA investigators found that Impax's investigation into the identification of metal contamination "d[id] not address the root cause" of the problem.

59. On June 15, 2010, Defendant Koch participated in a presentation at the Goldman Sachs Global Healthcare Conference. After prompting from an analyst's specific question about Form 483s, Koch finally divulged the existence of Impax's receipt of Form 483s, stating that Impax had "gotten a small number of minor 483s that [Impax] addressed promptly."

60. Koch further added that by this time in 2010, Impax had "perceived an increased level of scrutiny by the FDA" because the FDA was "sending more experienced teams" than previously, and "[s]o there [wa]s a clear focus on quality by the FDA." Koch stated that Impax had "been able to keep [its] reputation very high" and that, as part of Impax's "strategy from the beginning", Impax "c[ould]n't cut a corner on that." Despite the existence of the 2009 and 2010 Form 483s, which, together, had ***eleven*** formal Observations emanating from 18 incidents of inconsistencies with cGMP requirements, Koch nonetheless assured investors that "we've been able to enjoy a very good FDA inspection record" – despite the fact that FDA investigations guidelines state that all observations in a Form 483 are "significant objectionable conditions."

E. THE 2011 FORM 483

61. Impax received a Form 483 from the FDA on January 21, 2011, the final day of an FDA inspection that spanned two months. Prior to the FDA investigators' departure on that day, all inspectional observations listed in Form FDA 483 were read aloud to management during a close-out meeting that included Defendant Hsu, Mark Shaw (VP of Regulatory Affairs), Jeffrey Blumenfeld (Senior Director of Manufacturing), Emma Lin (Senior Regulatory Compliance Associate), Michelle Wong (Senior Director of Regulatory Affairs), May-Jih C. Chu (Senior VP of Operations), Robert S. Bertolani (VP of Quality Assurance), and Richard Ting (Senior VP of Research and Development). During this reading, investigators Peter E. Baker and William V. Millar stopped after reading aloud each sub-part to solicit questions, comments, and clarifications. Impax formally responded via a letter to the FDA on February 11, 2011. In the letter, Impax explained factors giving rise to the Observations in the Form 483, as well as its plan for remediation.

62. The 2011 Form 483 cited ***five*** Observations detailing deficiencies in the manufacturing process and auditing of the manufacturing process. They were: (1) failure to thoroughly review any unexplained discrepancy (officially marked a "REPEAT OBSERVATION"), discussed more fully below; (2) lack of control procedures to validate the performance of manufacturing processes potentially causing variability of in-process material; (3) failure to maintain equipment in a manner that would prevent malfunctions and contamination; (4) failure to follow and concurrently document process control procedures; and (5) failure to establish written procedures, precluding adherence to them, for annual evaluations of batch audits.

63. Set forth below are references from the 2011 Form 483 and accompanying EIR that that illustrate Impax's chronic inability to meet acceptable quality control standards. As discussed in the following subsections, these excerpts demonstrate that Impax was ***on notice*** of pervasive and severely deficient quality control practices and its inability to cure these issues (1) because the same FDA observation had been noted almost a year prior in a separate Form 483, (2) because other cited deficiencies violated explicit elements of ANDAs that Impax itself had previously submitted in writing to the FDA as conditional for approval, and (3) because the deficiencies were so egregious or numerous that Impax could not reasonably believe that they could be cured in a timely manner.

1. The Repeat Observation: Failure to Review Deviations as Mandated by 21 CFR § 211.192

64. Investigators recorded Observation 1 as "a repeat observation from inspection dated 4/7 – 4/22/2010." As a general matter for FDA investigators, it is "appropriate" (and they are thus not required) to indicate on a Form 483 when their observation of a significant GMP deficiency is a repeat observation from a prior Form 483 because it is an "observation made during a prior inspection [that] has not been corrected or is a recurring observation." Operations Manual 5.2.3. This indication by an FDA investigator has a heightened significance and may increase the likelihood of negative FDA action. At a minimum, the notation of a "repeat observation" demonstrates Impax's inability to remedy a serious objectionable condition that the FDA previously and expressly called to Defendants' attention.

65. The "repeat observation" on the 2011 Form 483 stated that there was "a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed." In explanation of only Observation 1, the Form 483 cited the unresolved presence of (1) continued metal contamination, (2) failure to identify the root cause of a vinegar-like odor in

one of Impax's drug products, (3) black specks present in another product and a ***three-year period during which Impax continued to use*** and failed to replace the faulty equipment producing the black specks, (4) unacceptable low and high weight deviation of individual pills, and (5) the use of powder ingredient instead of granular ingredient as required by the product specifications. (Emphasis added.) Each case was an example of how Impax staff "fail[ed] to thoroughly review any unexplained discrepancy" or to assess the impact that the deviation had on the finished product. The subsequent EIR that memorialized conversations that investigators had with Impax on these issues also noted that the deficiencies were a violation of 21 CFR § 211.192, which requires that "[a]ny unexplained discrepancy…to meet specifications shall be thoroughly investigated" and extended to other batches or other drug products "that may have been associated with the specific failure or discrepancy." Under § 211.192, a company also must create a written record of this investigation. *Id.*

66. The continuing metal contamination listed in Observation 1 as an example of Impax's failure to investigate deviations was notable because the FDA had explicitly cited this very problem in its 2010 Form 483. As such, investigators noted that Impax's "corrective and preventative actions are ineffective." In fact, the Company had initiated and ***closed*** four Corrective And Preventative Actions ("CAPAs"), despite that the metal contamination persisted, causing FDA investigators to conclude that the CAPAs had not corrected the root cause.[2]

67. As additional instances of failure to investigate deviations, FDA investigators noted two separate incidents, both relating to two batches of Fenofibrate (Nos. T001006, T006003) where there were problems with low weight capsules during Quality Assurance

[2] CAPAs are improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. CAPA is a concept within good manufacturing practice (GMP). It focuses on the systematic investigation of the root causes of non-conformities in an attempt to prevent their recurrence (for corrective action) or to prevent occurrence (for preventive action). http://en.wikipedia.org/wiki/Corrective_and_preventive_action.

sampling. In both cases, Impax employees did not investigate capsules other than those that failed during sampling. This practice was not consistent with GMP Regulations.

2. Violations of Impax's Abbreviated New Drug Application ("ANDA") Agreements with the FDA

68. FDA investigators Baker and Millar further explained in their EIR that Impax was in violation of at least two ANDA[3] agreements between Impax and the FDA. First, investigator Millar noted that use of a powder-form ingredient instead of granular, as noted under the Form 483 Observation 1, was disallowed by Impax's ANDA No. 77-833. Millar concluded that Impax "***has failed to maintain the commitments established with the [FDA]***." (Emphasis added.) Similarly, investigator Baker noted in the EIR that Impax was in violation of its standards reported in ANDA No. 75-868 because three batches of Fenofibrate capsules had been commercially released "without demonstration of a successful process validation, and without a high degree of assurance that the capsules produced through the manufacturing process meet the Quality standards identified by the firm in their FDA application." (Process validation is defined by the FDA as "the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process ***is capable*** of consistently delivering quality product." FDA, *Guidance for Industry: Process Validation* 3 (January 2011)) (emphasis added), *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070336.pdf (last visited on Sept. 10, 2013).

[3] ANDAs are "abbreviated" because they do not require normal lengthy human trials since they are for production of generics. *See* ANDA: Generics, *available at* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/ AbreviatedNewDrugApplicationANDAGenerics/.

3. General Deficiencies in Quality Control

(a) Impax Technicians Regularly Failed to Fill Batch Records in Real Time, as Required by cGMP Standards

69. During the FDA's inspection, Baker and Millar recorded in the Form 483 under Observation 4 and explained in the EIR that they observed instances of "multiple batch records that contained pre-filled information" where "controlled documents were being pre-filled by hand-written entries and stored until use." In addition to documenting this cGMP deficiency, investigators Baker and Millar discussed the problem with Impax management at the inspection close-out meeting on January 21, 2011, which included Hsu, Shaw, Blumenfeld, and Hildenbrand, among others. Baker and Millar also informed management of their belief that technicians were pre-filling forms "to 'save time.'"

70. Batch records are documents that comprise the raw data of what actually happened during the manufacturing process – they essentially act as "first responders" to quality control because they provide a record that can be investigated later as part of an investigation to resolve any deviations in the finished product. In addition, technicians' interaction with and sign-off of a task-by-task guide in itself facilitates accurate execution of required production standards and SOPs. As such, ***contemporaneous recordation*** of completed tasks and production data in batch records is vital to compliance with cGMP regulations, which ensure that the final product will have a reasonable likelihood of meeting the criteria that its labeling promises to the consumer. When a technician does not contemporaneously complete a batch record, there is a higher likelihood that the technician signs off on a task he or she has not actually completed.

71. CW 12, who worked at Impax from 2006 to 2012 as a Manufacturing Technician and Tooling Specialist, reported that technicians often pre-filled portions of batch records that were otherwise supposed to be checked-off in a step-by-step process after each individual task.

CW 12 observed Impax technicians fill-out batch records in a single sweep, which, according to CW 12, made technicians far more likely to check-off a step that they had not completed – even where SOPs are taken seriously. Compounding this problem was that QA's method for verifying equipment cleaning consists of checking the cleanliness of the room and the machinery at the conclusion of the technician's process. As such, QA simply could not audit whether each and every SOP step had been followed if the equipment appears clean.

72. The FDA's 2011 EIR highlighted another record deficiency. Investigators Millar and Baker noticed during their inspection what "appeared to be computer generated weight data in a trash can." A QC Technician explained that the data did not meet pre-weight requirements for testing samples and had to be re-weighed. When investigators asked about the provenance of the additional batch records required for the task, they found that the "additional batch record pages were not acquired per written procedure." Investigators noted in the EIR that the "significance of this observation is the firm's failure to account for all controlled documents" and that "[w]ithout traceability, the quality unit lacks assurance that all records associated with the batch are accounted." Otherwise doing so, would ensure that quality checks took account of "re-weighing activities being performed."

(b) Impax Took Shortcuts and Undermined Quality Control Testing

73. Continuously throughout the FDA's issuance of Form 483s from 2009 through 2013, investigators cited Impax for its failure to fully investigate deviations in the production process. As for those investigations that Impax actually did do, investigators Baker and Millar noted in the 2011 EIR that Impax's internal investigations "often rel[ied] on a review of routine in-process control data to justify the acceptability of drug products following the identification of a manufacturing deviation." Investigator Baker explained more fully in the FDA's EIR that "a

review of limited routine in-process sampling is not considered an investigation." In short, Impax "relies too much on analytical testing and results to justify the acceptability of an unexpected product." In particular, investigator Baker recorded four examples of this problem. The first was that when powder-grade ingredient had been used for a product requiring granular-grade, Impax staff erroneously stated that an investigation was not required because "each of the batches met…testing during initial release."

74. The second incident that the FDA investigators recorded in support of this negative trend was that Impax staff had observed "black specks" in Colestipol HCl tablets 1g, but had not adequately investigated the extent to which all product might be contaminated with black specks. Both Baker and Millar told Impax management that "the firm relies too much" on "release testing." This trend was problematic because the Quality Control testing calibrated for production of Colestipol HCl "does not analyze for foreign material such as 'black specks.'" And thus "routine in-process sampling is not considered a thorough investigation, given the nature of the risk." Nonetheless, Impax staff had been using superfluous test results to sign-off on the integrity of a clearly adulterated product.

(c) Impax Failed to Properly Maintain Equipment or Phase-Out Equipment that Had Exhausted its Commercial Life Span and Capability to Meet cGMP Standards

75. During the inspection leading to the 2011 Form 483, FDA inspectors had a second meeting with Jahn and Huettig. CW 13 heard from colleagues that the investigators communicated their belief that Impax needed to replace its old machinery. CW 13 said that Jahn's response to the FDA's conclusion was that "'we maintain our equipment very well, which is why we use old equipment.'" According to CW 13, Jahn was regularly very critical of the QA department and claimed that they would not pass FDA inspection. Jahn's stance as he stated to

CW 13 was that Quality Assurance employees "don't know what … they were doing. The SOPs are not right.'"

76. Under the Form 483's Observation 3, investigators described examples of Impax's failure to maintain equipment and utensils "at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product." One example was the presence of two liquid droplets investigators observed on one of Impax's tablet presses. "The location of the droplets are [redacted] where product blend is compressed into tablet form." Moreover, the tablet press also had chipping paint on equipment parts that were located above the tablet compression. Both conditions posed a danger that paint could drop into the actual drug product during production.

77. This issue was long-standing. Six months after joining Impax in 2008, CW 13 – whose role it was to repair and document the status of the manufacturing machinery – complained specifically to Jahn about Impax's aging machinery. According to CW 13, because of their decades-old age, Impax's outdated tablet presses were bad for product integrity. CW 10 likewise stated that CW 10 recalled discussions in Chuck Hildebrand's (VP of Operations) weekly staff meetings, as well as CW 10's one-on-one meetings with Jeff Blumenfeld, in which they discussed the company's need for new equipment. Antiquated equipment was a problem, according to CW 10, but "Larry [Hsu] wouldn't buy new machines." Impax "constantly priced machines out and it came into discussion at Chuck [Hildenbrand]'s staff meetings" because Impax had "a high degree of delays because of rejected [product] batches."

78. At least one machine in particular, had a faulty lubrication line that repeatedly sprang leaks – as soon as one was repaired, another leak would start. CW 13 stated that "it had been going on for a long time due to the machine being old and dated." Moreover, this machine

had chipping paint. CW 13 had prior experience in FDA-regulated facilities, and, to CW 13, it was clear that "you can't have painted equipment chipping and making things that are eaten by the consumer." As such, CW 13 regularly "would try to tell Jahn that we needed to get new equipment." But Jahn and CW 13 had a history of disagreeing on how to maintain equipment and also the best solution for the limitations caused by Impax's aging machinery. Jahn told CW 13 that new machines take too long and too much money to purchase and validate for use. Instead, Jahn's solution was to strip the paint and cover the machine in clear lacquer. This was no solution, according to CW 13, because the alcohol wipes used in the cleaning process stripped the lacquer, exposing porous metal where bacteria or mold could fester and pose contamination issues.

79. Jahn was not the only person to whom CW 13 complained. "I talked to guys in my department about paint getting in the pills." CW 13 recalled having conversations about the paint chipping off the machinery with Pierre Dubois, who was a Supervisor, as well as Blumenfeld (Senior Director of Manufacturing). CW 13 stated that "Blumenfeld listened to me. He said 'duly noted.' "

80. The FDA investigators inspected and inquired about this very machine, as memorialized in their EIR. Regardless of the reason for the leaky lubrication arm, investigators noted that the "significance of this observation is that both objectionable conditions" – the lubrication leak and the chipping paint – "indicated that the [redacted] is not properly maintained. Leaking lubrication and chipping paint ***are not expected or acceptable conditions for this equipment***" and, according to the FDA investigators, could lead to contamination of drug product. (Emphasis added.) In fact, prior to the preparation of the EIR, one of the investigators'

contemporaneous notes taken during the investigation itself, stated that he was "very concerned" about the condition of the machine.

81. There were several communications between Impax and the FDA regarding this particular tablet press and its condition that illustrate Impax's inability to remedy problems. Despite CW 13's complaints about the actual condition of the machine, Jahn told FDA investigator Millar, as memorialized in the EIR, that the true cause of the lubrication leaks had to do with the existence of two power switches. According to Jahn, if a technician flipped one switch but forgot to flip the second switch, the lubrication pump remained powered on and would push out extra lubrication. Weeks later, when Mark Shaw signed a response letter to the FDA on June 27, 2011 that included a discussion of this machine, Impax explained that the lubrication line was on a timer and that the leak happened after the entire machine had been powered on too long (without use) in anticipation of the FDA investigators' evaluation that day. Neither Jahn's explanation nor Impax's written response revealed that the machine was actually in a chronic state of disrepair, as evidenced by CW 13's consistent experience fixing leaks – a compelling indicator that the machine may simply have been too old for continued commercial use but was still part of production at Impax.

82. Indeed, CW 2 reported that the FDA investigators took issue with warped machines that had paint chippings, and told Impax that "'these machines need to be retired.'" Yet, CW 2 reported, management did not want to retire the machines. Instead, Impax employees repainted the machines and resurfaced machine cables. CW 2 added, "we were making it better, but didn't fix the problem." Indeed, Impax "had been running like this for a long time. We didn't know any better."

83. In similar manner, Impax's years-long struggle with solving metal contamination further demonstrates an inability to timely identify the cause of major, chronic problems. According to CW 1, shortly after the Warning Letter, Impax discovered that a vibroscreen caused metal shaving product contaminations. But CW 3 stated that one a manufacturing supervisor discovered that bolts securing the guides on the tablet press, too, were causing metal shavings. Then, it its June 27, 2011 response letter to the FDA, Impax stated that it had "engaged quality engineering consultants to assess all investigations related to metal detector rejects" of tablets. By January 18, 2012, in its ongoing correspondence with the FDA – and nearly ***two years*** after the FDA's observation during its 2010 inspection of a failure to identify the root cause of metal contamination – Impax further elaborated that "Impax has identified several definitive root causes that contribute metal into the process based upon multiple investigations and complete in-depth review of all process equipment." In short, Impax took nearly two years to claim that it identified the "***several***" root causes of metal contamination – and did so ***only after*** receiving two Form 483s identifying the same "repeat observation" which had also already escalated to a Warning Letter for the same problem.

84. In yet another instance, investigators Baker and Millar recorded in the Form 483's Observation 1 that Impax employees had observed "black specks" in Colestipol HCl tablets 1g in November 2006. As explained more fully in the EIR, though Impax "was aware that their own tablet compression equipment…was causing charring" that showed as black specks in the tablets, Impax "failed to replace the equipment." This exact equipment remained in use, and Impax technicians again recorded observations of black specks in tablets produced in May 2010, causing investigators to stress that "over three (3) years has elapsed since the firm's first observation of 'black specks.'" Impax employees had only been using a visual check to monitor for black

specks; yet as FDA investigators critically noted "these in-process checks only verify the surface area of the tablets" and thus were inadequate.

(d) Impax Misled FDA Investigators

85. During the December 2010 to January 2011 inspection, investigator Millar gave management a "verbal warning" for misleading the inspection team. Kangwen Lin, Director of Technical Services, had misled investigator Baker by referring several times to the metal contamination in Oxymorphone HCL extended-release as "grey particulates." She continued to do so until Baker presented her with documentation that the grey particulates were in fact metal. Lin then admitted that substance was metal. After this incident, investigator Millar gave a verbal warning to Lin as well as Shaw (VP of Regulatory Affairs and Compliance), Osani (Sr. Manager of Regulatory Compliance), and Baier (Technical Services and Assoc. Dir. of Manufacturing). In the warning, investigator Millar reminded Impax management that misleading federal investigators is a federal offense.

F. THE CLASS PERIOD BEGINS AS IMPAX RECEIVES A WARNING LETTER FROM THE FDA

86. Ultimately, the FDA could no longer tolerate Impax's abysmal record of non-compliance and its inability to correct its repeated violations of significant FDA regulations. As a result, the FDA through Bay Area District Director, Barbara Cassens, issued a Warning Letter to Impax, addressed to Defendant Hsu on May 31, 2011. Afterward, Impax disclosed the receipt of the Warning Letter in a press release dated June 6, 2011. The Warning Letter underscored "significant violations of Current Good Manufacturing Practice (cGMP) regulations for Finished Pharmaceuticals." In particular, the Warning Letter informed Impax that the FDA had "reviewed [Impax's] response" to the January 21, 2011 Form 483 that Impax had submitted on February 11,

2011 under Mark Shaw's signature "and note[d] it ***lacks sufficient corrective actions***." (Emphasis added.)

87. The Warning Letter cited two categories of practices that violate FDA standards that had been cited among the 2011 Form 483's five Observations: (1) lack of written procedures to "monitor and to validate" manufacturing processes that could have been responsible for variability in finished product (citing 21 C.F.R. § 211.110(a)), and (2) the failure to investigate deviations in the manufacturing process. For the first Observation, the FDA again cited deficiencies identified in the 2011 Form 483: Impax's failure to demonstrate that the manufacturing process for Fenofibrate 200 mg capsules could control the weight variations and that the process for Colestipol Hydrochloride 1g tablets contained appropriate heat temperatures. For the second Observation, the FDA cited Impax for the repeat Observation from the 2010 and 2011 Form 483s: Impax continued to fail to thoroughly investigate batches that did not meet specifications. As an example, Impax had not solved the metal contamination problem.

88. Due to Impax's materially false and misleading statements assuring investors that Impax had already implemented changes to address QC issues, as discussed more fully below, analysts and the market responded cautiously but optimistically to Impax's announcement on June 6, 2011 that it had received a Warning Letter. Two days later on June 10, 2011, Wells Fargo Securities, LLC published an analyst report in which it reported that Impax had received a Warning Letter, and stated that the "Warning Letter will likely cause a ***temporary*** halt to approval of pending ANDA applications from the Hayward facility." (Emphasis added.) The report further stated that the issues cited in the Warning Letter "***appear fixable,*** and should have ***no long term negative impact*** on IPXL [Impax], in our view." (Emphasis added.)

89. After additional misleading statements detailed below, the market's cautious optimism persisted. On November 1, 2011, Wells Fargo Securities LLC issued an analyst report in which it reported a key takeaway that management was "optimistic about [the] potential resolution of FDA Warning Letter by end of February 2012" and that Impax was "on track" for its fourth quarter NDA filing in support of Rytary (referred to as "IPX066" for proprietary reasons prior to disclosure). Wells Fargo also stated "***We are encouraged*** by m[anagement]'s focus in resolving the FDA Warning Letter, but exact timing is dependent on FDA re-inspection." (Emphasis added).

90. The FDA's issuance of a Warning Letter to Impax would unleash a series of back-and-forth communications that further demonstrated to Defendants just how pervasive Impax's cGMP problems were. Mark Shaw (VP of Regulatory Affairs and Compliance) signed an initial response to the FDA on June 27, 2011, with an attached and lengthy detail of the remedial measures that Impax intended to implement. In the letter, Impax also admitted that "surface inspection by itself is not a satisfactory method to confirm or dismiss metal contamination" but assured the FDA that visual inspections were not the full extent of its metal contamination detection procedures. Impax proposed an updated SOP for metal detection and that would become effective the following month. Then on August 5, 2011, Mark Shaw again wrote a letter to the FDA, enclosing "additional planned corrective actions." On September 9, 2011, Jeff Nornhold wrote another follow-up letter to the initial June response, enumerating even more "additional corrective actions" and completing supplements to Impax's response to the Warning Letter.

91. In response to these communications, the FDA wrote a letter to Impax dated October 4, 2011, requesting "additional details" and "clarification" of Impax's responses, and the

FDA letter referenced specific items in the Warning Letter. Despite the new SOP detailed in Impax's June 27th letter and Impax's follow-up communications to the FDA, described above, the FDA nonetheless found significant deficiencies in Impax's corrective measures. The FDA's October 4th letter stated that the FDA "remain[ed] concern[ed] with the corrective and preventative actions to the metal contamination in [Impax's] drug products" because even under Impax's proposed new metal detection process as detailed in its June 27th letter, the Company "continue[d] to rely on surface inspection of 'second pass rejects' as described" in its new SOP 2MFG-049.11. The FDA reminded Impax that "surface inspection by itself is not a satisfactory method to confirm or dismiss metal contamination." Moreover, the FDA concluded, Impax had still – three months later – failed to show the FDA that Impax had "identified the root cause(s) of the metal contamination."

92. Ten days later, Nornhold replied with a follow-up letter to the FDA dated October 14, 2011 and provided supporting documents. Two months later on December 2, 2011, Nornhold wrote another letter to the FDA in reference to a November 23, 2011 phone call Impax had with Carl Lee, the FDA district office compliance officer. In this letter, Nornhold explained that Impax would push back a date to provide the FDA updated data in connection with the FDA's October 4th request for more information (specifically in reference to Warning Letter Item Nos. 1(a) and 1(b)). Later, on January 5, 2012, Nornhold wrote yet another letter to the FDA discussing CAPAs that had been implemented in response to the FDA's concerns about Fenofibrate capsules as cited in the Warning Letter and as the basis for the FDA's request for follow up in the October 4, 2011. Finally, on January 18, 2012, Nornhold wrote a letter reporting that Impax had completed the validation process referenced in its December 4th letter announcing an extension and reporting the results. As such, Impax's full response to the May 2011 Warning

Letter took over six months from the date of its issuance to complete – a precursor to the FDA's process, which also necessitated an onsite reinspection, as part of the timeline for resolution of the Warning Letter.

G. THE 2012 FORM 483

93. On March 28, 2012, Impax received yet another Form 483 from the FDA through its investigators Baker and Millar. The 2012 Form 483 contained ***five*** Observations, supported by twenty separate example incidents. In particular, it cited three Observations relevant to practices in the QC Laboratory: (1) drug products that failed to meet established standards were not rejected; (2) investigations into the failure of a particular batch did not extend into other batches of the same product; and (3) SOPs for testing and sampling were not followed. Yet Observations 4 and 5 were directly relevant to manufacturing practices.

94. Despite that Impax had brought in a consulting firm, TEVA, to audit its manufacturing facility shortly before the March 2012 Form 483, as CW 3 reported, Impax nonetheless received an Observation dedicated solely to cGMP deficiencies in manufacturing. Observation 4 targeted Impax's failure to follow "written production and process control procedures" and was directly relevant to the manufacturing process. As examples, investigators Baker and Millar noted that equipment was incorrectly stored in a manufacturing room being used for production and sometimes contained unidentified product residue. Additionally, equipment failures that required non-routine maintenance were not consistently investigated: out-of-service notifications had been issued but no investigation had been conducted on three occasions regarding machines used in the tablet compression process and the granulation processes.

95. Moreover, Observation 5 was relevant to both manufacturing and the QC Lab – most notably, it echoed the same chronic failure on the part of Impax to fully ***investigate deviations and their root causes*** that had been cited every year in Form 483s since 2009. Observation 5 noted a "failure to document and investigate discrepancies that arise during the course of manufacturing and QC analytical testing" such as, among various examples, "unexpected manufacturing discrepancies, including but not limited to critical equipment failures."

96. Contrary to the characterizations espoused by Defendants, and explained more fully below, the 2012 Form 483 was not unexpectedly targeted to a wholly new area of investigation because (1) consistent with previous FDA observations, it also cited Impax's lack of complete and fully documented investigations into deviations – a pervasive and consistent problem cited annually in Form 483s since 2009 – that had now been shown to also extend to the QC Lab as well as manufacturing; and (2) the Form 483 did in fact include deficiencies related to manufacturing, including the familiar observation that Impax failed to fully document its investigation into unexplained discrepancies "during the course of manufacturing". In fact, the relevance of Observations 4 and 5 to manufacturing practices is important information because Impax made various public statements after the issuance of this Form 483 that it pertained ***only*** to the QC Lab, and its SEC filings on the matter stated that the Form 483 pertained "predominantly" to the QC Lab while giving no further details that any other department was involved, such as manufacturing. Moreover, and contrary to Defendant Hsu's later public statements as explained below, the 2012 Form 483 ***did not*** hinge on Impax's ignorance to the fact that "trial injection" methods had become disfavored by the FDA, because (1) only Observation 1, out of ***five*** Observations, targeted trial injection practices, and (2) even Observation 1 did not state that the

testing method itself was inconsistent with cGMPs, but that Impax's practices themselves were, because FDA investigators found in ten instances that there was "no documentation and/or investigation to provide assurance that the 'trial' and 'official' samples were performed using the same sample/lot under analysis."

97. During this same period, at the June 7, 2012 Goldman Sachs Global Healthcare Conference, the June 29, 2012 Wells Fargo Securities Research Health Care Conference, and the UBS Global Life Sciences Conference that took place on September 20, 2012, Impax repeatedly and falsely stressed that the inspection leading to the 2012 Form 483 was unexpected and independent from the inspection issues giving rise to the Warning Letter. However, as noted above, the 2012 Form 483 did contain Observations related to chronic QC problems – such as failure to fully investigate or document deviations – which had been similarly noted in the Warning Letter and in previous Form 483s.

98. Due to Impax's repeated mischaracterization of the contents of the 2012 Form 483, analysts cautiously but positively responded to these repeated announcements. For instance, J.P.Morgan issued an analyst report on July 31, 2012, in which it stated that management at Impax "remains cautiously optimistic about near-term resolution of the Hayward Warning Letter." That day, both the price and trading volume spiked for Impax stock: the price per share went from $20.51 at a trading volume of 389,303 on July 30th to $22.22.

H. THE TRUTH IS REVEALED AS IMPAX RECEIVES ITS FIFTH FORM 483 AND STILL IS UNABLE TO CLEAR THE WARNING LETTER

99. On February 28, 2013 the FDA through Daniel J. Roberts, an investigator, and Walden H. Lee and Kim L. Thomas Cruse, both chemists, authored yet another Form 483 issued to Impax and containing ***twelve*** Observations. Hsu would report to securities analysts in Impax's

March 4, 2013 Ryatary Update Call and in a press release that same day, that this 2013 Form 483 contained three repeat observations. At least one of those three repeated a substantially similar failure in protocol that had been cited and repeated in the Form 483s from 2009, 2010, 2011, and 2012. Observation 3, yet again, repeated a theme present and unresolved since 2009: investigators had observed "a ***failure to thoroughly review an unexplained discrepancy*** and the failure of the batch or any of its components to meet…specifications…"

100. In sum, Observation Nos. 1 and 2 hinged on quality control: (1) the integrity of test methods had not been independently established, and (2) control procedures to "validate" manufacturing processes that may be responsible for variability in the manufacturing process had not been established. Observation Nos. 4 - 11 objected to a lack of controls that disallowed unauthorized employees to make changes in master production records; inadequate SOPs; insufficient batch records; failure to independently test component suppliers' products; failure to properly store drug products; failure to adequately document changes in certain SOPs; failure to follow SOPs for warehouse storage; and failure to follow SOPs concerning complaints and recalls. Separately, Observation 12 acknowledged that "[e]mployees engaged in the manufacture and processing of a drug product ***lack the training and experience required to perform*** their assigned functions." (Emphasis added.)

VII. APART FROM WHAT DEFENDANTS LEARNED FROM THE FDA, THEY INDEPENDENTLY KNEW OR RECKLESSLY DISREGARDED THE FACT THAT IMPAX HAD SIGNIFICANT, PERVASIVE MANUFACTURING AND QUALITY CONTROL DEFICIENCIES AND THEY HAD NO REASONABLE BASIS TO ASSURE INVESTORS THAT IMPAX WAS CAPABLE OF CLEARING THE WARNING LETTER IN A TIMELY MANNER

101. Though Defendants were in receipt of numerous Observations consistent with an ongoing problem dating back to at least 2009, Defendants continued to maintain to the public that they had already implemented sufficient remedial measures to resolve FDA Observations and to

quell further negative inspections. Yet Impax and its senior management – based on information available and well-known at the Company – had no reasonable basis to assure investors that they had the capacity to resolve their problems with the FDA and to successfully resolve the Warning Letter in the foreseeable future: failure to follow cGMPs and other FDA regulations was a pervasive, severe, and longstanding problem that previous responses to Form 483s in at least 2009, 2010, and 2011 had failed to resolve.

A. IMPAX IMPLEMENTED AND THEN REVERSED CORRECTIVE MEASURES TO GIVE THE IMPRESSION OF COMPLIANCE AND SET-UP DECEPTIVE LAYOUTS FOR THE DURATION OF INSPECTIONS

102. According to CW 1, Impax often made temporary changes to their processes and then quickly reverted back to Impax's original practices once the FDA inspection ended. "Impax had a policy to put a Band-Aid on it temporarily," CW 1 said. For example, CW 1 recalled that sometime after the May 2011 Warning Letter, between 2011 and 2013, the FDA instructed Impax to place its raw materials, compounding materials, compression materials, and coating materials (ingredients related to the four separate phases of production) in separate rooms to avoid cross contamination because such contamination could result in death for some patients. Impax had been storing all the materials together in the same room located in the Building 5 warehouse. In response, Impax removed equipment from a "clean room," installed shelves, and placed some of the materials in this room. About one week after the FDA investigators left, Impax returned the materials placed in the clean room to their original location in the main warehouse, re-exposing them to potential cross-contamination.

103. CW 5 stated that due to the lack of space in the manufacturing facility, technicians were "constantly moving equipment from room to room" because there was not enough storage space in the facility for all of the equipment. In addition to the "jockeying of equipment," the

company made plans to expand the cleaning rooms, but none of the plans were carried out during CW 5's employment which spanned from 2002 through 2012. According to CW 5, if Impax knew the FDA was coming to inspect, manufacturing technicians were ordered to spread equipment out to other rooms to conceal the company's space issues. In anticipation of an FDA inspection, the Company also stopped production of certain products because the products created too much dust and the FDA would likely cite Impax for the dust. "We did not have enough dust collection on tablet presses. The rooms were not set up for that. We didn't have new vacuum pickups."

104. CW 6 echoed others' concerns about the lack of space: "The contention that we were running out of space was absolutely legitimate. Our washrooms were undersized. You can't miracle yourself a bigger plant."

105. CW 11, a Warehouse Supervisor, reported that a few weeks prior to the 2012 and 2013 FDA inspections, Ron Valine, a Warehouse Manager, and Luis Kolb ordered CW 11 to move equipment and supplies from the manufacturing facility and place them in non-GMP warehouses owned by Impax. CW 11 believed that Impax "wanted to hide stuff from the FDA." CW 11 came to this conclusion based on the fact that transfer of materials occurred just prior to each FDA inspection in 2012 and 2013, and because CW 11 had experience working in a GMP warehousing at Hewlett Packard, so CW 11 understood FDA protocol. Impax was "cleaning up for the FDA. Taking junk out of the building. They were housecleaning."

106. In 2011, Valine and Kolb ordered CW 11 to clear a warehouse in back of Impax's Building 10, where Impax had been storing documents and equipment, from the R&D building and manufacturing facility, respectively. A third-party moving company moved the documents and equipment from Building 10 to a larger warehouse in Building 11, which was located on

Zephyr Road and was a brief walk from the executive office building on Genstar Road. "A few weeks prior" to the March 2012 FDA inspection, Valine and Kolb ordered CW 11 to move equipment from the manufacturing facility to Building 11. The warehouses in Building 11 where CW 11 moved materials were being renovated and were neither clean nor secure. There were "spiders climbing" around equipment and up into equipment hoods. In fact, when CW 11 moved materials to Building 11 again in late 2012, just prior to the January 2013 FDA inspection, the building was still in the process of being remodeled. "I don't think the FDA knew about [Building 11]." Kolb made the decision to move the materials prior to both FDA inspections.

107. CW 11 retrieved the equipment and supplies from hallways in the manufacturing facility. The manufacturing facility, due to its inadequate size, was overflowing with equipment. When it was time to pick up the equipment, CW 11 received emails from manufacturing supervisors, as well as production engineering employees that reported to Raymond Jahn; also, little notes were placed on items in the manufacturing facility that signaled CW 11 to move them to Building 11. After the FDA inspections were conducted, CW 11 would receive requests to bring certain supplies or equipment back to the manufacturing facility. "As requested, stuff was moved back to the manufacturing facility." CW 11 recalled that Luis Kolb, Ron Valine, Mark Fitch, and Shaheed Mohamed (who was a Warehouse Supervisor), were all aware of this pattern of movement of materials in pace with FDA inspections.

108. Shortly before the January 2013 FDA inspection, Kolb instructed CW 11 to coordinate with R&D Operations Manager Mei-shel Hon the removal of documents from Building 8, which was the location of Impax's Research & Development division. Johnson Ling, who reported to Mei-shel Hon, assisted CW 11 with moving the documents from Building 8 to Building 11. CW 11 recalled seeing a total of 30 pallets of documents moved from Building 8 to

Building 11. Impax did not follow proper SOPs when transferring the documents because CW 11 did not sign any transfer documents that would have enabled the company to track the documents. Furthermore, CW 11 said, "Documents need to be in a secure building. There was no security at Building 11." In fact, nobody worked in Building 11, which meant the documents could have been accessed, altered and/or damaged, according to CW 11.

109. CW 1 complained directly to a supervisor about the practice of temporary and reversed improvement measures, and was not the only technician to complain. That supervisor told CW 1 that other employees had also voiced the same complaint. CW 1 further stated that the complaints CW 1 generally heard others say to supervising staff at Impax was, "'You guys are doing it just to get away from the FDA.'"

B. CLEANLINESS AND SANITATION WAS CONSISTENTLY A PROBLEM

1. FDA-Compliant Procedures Were Not Followed in Response to Events of Possible Contamination

110. CW 13 reported that between 2008 to 2010 two of the Glatt machines that "coat the little BBs [of drug product] inside capsules" were consistently blowing their explosion-proof panels approximately once every two weeks. When a panel blows, it comes off the machine and the product being produced is exposed to the atmosphere making it susceptible to contamination. When this happened, Impax technicians were supposed to stop production for half a day and sterilize the machinery. In late 2009 or early 2010, when CW 13 was notified that one of the panels had blown, Luz Ludesma and Jeff Blumenfeld instructed CW 13 and Arnel Swan ("Swan"), who was a maintenance instrument technician, to keep the machines running instead of shutting them down for sterilization. CW 13 stated that there have been three or four occasions when CW 13 was instructed to keep the machines running after panels had blown. At the time,

Impax was producing Tamsulosin, a very profitable drug, on the machines. Shutting down a Glatt for half a day could cost Impax $20,000.

111. On one of the occasions where the Glatt machine blew its panels but CW 13 was instructed not to stop operations, Swan told CW 13 that "this is going in my black book" – in reference to a book of notes he kept of every instance he witnessed where Impax violated procedures. Swan informed CW 13 that Swan had "enough info[rmation] in there to bring the whole factory down."

112. CW 13 echoed other witnesses' reports that the size of Impax's manufacturing facility and its cleanliness were consistently deficient. CW 13 also recalled standing on a second-story balcony in the manufacturing facility that overlooked the "clean rooms" and seeing dust all over the ceilings of the rooms – drop ceilings that were porous and also had gaps where bacteria could grow or contaminating substances could be trapped and eventually penetrate the clean room. (Clean rooms were places where cleaned and sterilized equipment was stored.)

113. Concerns about cleanliness and sanitary conditions continued to be expressed during the Class Period. CW 5 concurred that manufacturing technicians made complaints at town hall meetings that executive members held in the manufacturing facility, voicing their concerns about the lack of appropriate space for cleaning equipment. CW5 emphasized that "the cleaning areas we had were not sufficient." For example, there were rooms that had only two little sinks, but technicians were expected to wash big pieces of equipment in the sinks, resulting in water splashing around the room. "When you're hosing equipment down and stuff, stuff splashes all over the place," said CW 5. These factors meant that "there was a possibility for cross contamination."

2. Employees Found Insects in Manufacturing Areas

114. In February 2011, CW 4 found an insect in the main weighing room. She told another manufacturing technician, Sophia Pusio, about the insect and Pusio told CW 4 that Pusio had also found insects in the weighing room in the past. Pusio recounted to CW 4 how Pusio had gone directly to the shift manager, Sulaman Ahmad, and told him that she had found insects in the weighing room and knew where the insects were coming from. Company procedures required a technician to stop processing a batch if insects were found, but Ahmad instructed Pusio to "just keep going." He told Pusio to pretend as though she had never seen the insects. Before CW 4 could report to a team lead or supervisor that CW 4 found an insect, CW 4 was encouraged by fellow, more senior technicians to drop the matter. During the course of about six years of employment, CW 12 found about seven or eight bugs in the manufacturing facility's production area. CW 12 stated that CW 12 bagged the bugs and brought them to QC staff for inspection, but that production was never stopped when CW 12 found and caught bugs.

C. DOCUMENTATION AND BATCH RECORDS WERE EGREGIOUSLY BELOW ACCEPTABLE FDA STANDARDS

115. In June 2011, just shortly after Impax's receipt of the May 31, 2011 Warning Letter, Michael Yoon stated to CW 13 in a conversation that the two had that "Impax was in trouble. The writing was on the wall." (Though CW 13's employment ended in May 2011, CW 13 remained in contact with Yoon.) As a managerial employee in Human Resources, Yoon reviewed employee matters and interacted directly with many personnel from various departments. Yoon further stated to CW 13 during this conversation that the paperwork in QC was "terrible."

116. CW 2 recalled that after the May 2011 Warning Letter, Impax management pressured supervisors to correct problems, with a focus only on the end result: to wrap-up

paperwork and close investigations. (According to CW 2, investigation reports interrupt the pace of the manufacturing process, whereas incident reports do not. Both types of reports generate documentation.) If staff did not have a definitive answer for the root cause of problems, they often made up a cause. CW 2 recalled that Keith Lee, a Manufacturing Compliance Manager, "was more concerned about the timeline" of paperwork completion than about determining the true cause of a problem. Lee worked in the front office, mostly reviewing paperwork, and did not work on the manufacturing floor.

117. According to CW 2, in a particular incident, an investigation report had been initiated because Quality Control had found metal shavings in one of the machines that spray coating on tablets, called a "coater." CW 2 described how Lee attributed the shavings to a source that, in CW 2's assessment, was not the root cause. A fellow operator blamed the metal contamination on a dented spray arm that, CW 2 explained, could not be the source because the arm is always immobile and did not move, rub, or slide against any other piece of machinery during the spray process. (Alternatively, the arm can bump the door rim when the machine is opened and closed, but CW 2 stated this would not cause shavings as found.) When CW 2 asked Lee about this investigation, Lee told CW 2 "I'm only doing what the operators told me." According to CW 2, Lee "just wanted to close the investigation report."

118. CW 4 reported that manufacturing technicians had the habit of writing "entry error" on batch records instead of explaining what caused the error, which was required. The practice of simply writing "entry error" on any amendments to batch records continued the entire time while CW 4 worked at Impax. Detailed and adequate batch records are vital, not only by cGMP standards but, as CW 6 stated, "When you're batch manufacturing and you're using a batch record, there are always small decisions that have to be made along the process. And

tech[nician]s typically make notes about what is going on." CW 6 explained that technicians' batch records go through a formal quality assurance audit through a few layers of review. As such, clear and complete notations are vital. Such shortcuts were not limited to the production of product.

119. CW 12, a Tooling Specialist who spent significant time on the manufacturing floor, stated that Impax did not have documented proof that it was maintaining cleanliness standards. "It's just the way the company was being run." Impax had grown too quickly, and it "didn't have checks and balance system in place; no one checked to see that things were done correctly." The Company "might not have had the workforces to maintain checks and balances. A lot of documentation was missing…. There were a lot of holes in the system."

120. CW 6 further explained that "it was not well documented why we made the choices we did." The FDA was thus justified when it expressed concern in its 2011 Form 483 over Impax's lack of validation processes – in short, Impax insufficiently documented and justified the scientific reasons for its manufacturing processes.

121. CW 7, a quality assurance consultant working as part of a group from Validant at Impax in the summer of 2012, reviewed four years of data in the R&D technicians' lab notebooks, which included notations about parameters set on instruments, concentrations of solvents, and other standards that would enable another technician to duplicate the process. The R&D group developed methods that the Company later used to test products in the QC Lab for safety and efficiency: if there are flaws not caught during development, there can be problems later and with the consumer. On the R&D side, "anytime [lab technicians] performed a test or did development activities, they recorded everything they did in a notebook." CW 7 stated that "we

did find things. We did find things that, in my opinion, were concerning. Impax hadn't documented things that were required by the FDA."

122. In CW 7's investigation of R&D data, CW 7 and the other consultants observed repeated instances of Impax's failure to provide an explanation for a technician's decision to retest samples. "When you run a test and something doesn't go as expected and you have to start the test over, it could be because the machinery is not working or it could be because you didn't get the result you wanted." Thus there are benign reasons to rerun a test. But "if the reason is that you're just running the test again because you want different results, that's a problem." For this reason, the technician "needs to document why" something was retested. Yet "many times, test samples were tested and retested without any explanation." CW 7 also observed instances where employees overwrote another technician's data without a sufficient explanation of the reason for the change. This correction is not per se problematic, if justified by circumstances such as the correcting author's presence at the original test. But there were instances of bare corrections with no justification at all, let alone an acceptable one.

123. CW 7 recalled how "Impax recorded data in a convoluted way." Data generated from instruments was stored in lab notebooks as well as data packets, which were manila folders that were kept separate from the notebooks. Impax had no system to tie the lab notebooks and data packets together. "It can be difficult to link these two, even though they have similar information." CW 7's team did not feel comfortable resolving ten or twelve investigations into unexplained data due to their inability to explain the data gaps. Normally, CAPAs, which garner the establishment of new training and practices, would be issued to makes sure the problems do not happen again. However, according to CW 7, CW 7's team "was not encouraged to initiate

CAPAs. That wasn't what [Impax] wanted us to do." Instead, they turned over the ten or twelve open investigations to Steve Fields.

D. IMPAX MACHINERY WAS ANTIQUATED AND SO FREQUENTLY NEEDED REPAIR THAT COMPLIANCE WITH GMP REGULATIONS WAS NOT POSSIBLE

124. In addition to CW testimony detailed above and describing instances of aging machines that could not achieve consistent, safe operation even with numerous maintenance repairs, other CW testimony confirms the pervasive nature of machines in disrepair. CW 2 explained that as early as the 2010 FDA inspection, "things got turned upside down." The intensity of the 2010 FDA inspection was unlike previous years because, for the first time that CW 2 and many other saw, an FDA investigator showed up at Impax with a camera. "It was very unusual. Keith [Lee, a Manufacturing Compliance Manager] was blown away by that." CW 2 also explained that so many machines were in need of service that Impax employees had placed numerous "fix-it notes" on them during the 2010 FDA inspection that explained to the FDA that Impax was working on correcting an issue with the machine. CW 3 corroborated CW 2's account, stating that Impax's equipment was antiquated, and the building space itself was inadequate with regards to space and portable equipment.

E. IMPAX COULD NOT ERADICATE METAL CONTAMINATION IN A REASONABLE AMOUNT OF TIME

125. After the May 2011 warning letter, Eric Baier, the Associate Director of Manufacturing, told CW 2 that "'There's no way we are going to get rid of it [metal contamination].'" CW 2 understood that the reason supporting this sense of defeat was that, throughout the manufacturing process, there are instances of metal on metal, making some level of contamination inevitable. Separately, CW 1 remarked that the FDA's finding of metal

contamination in over 70% of Impax's finished product, was a "very high" number because acceptable levels "should be less than 3%." CW 3 also called the number "quite startling."

126. According to CW 1, up until the May 2011 Warning Letter, Impax's practice had been to detect metal contamination predominantly through bare visual inspection. CW 1 stated that after the Warning Letter CW 1 received an award for discovering that the source of metal shavings were coming from a vibroscreen. Additionally, CW 3 stated that a supervisor discovered through internal audits that bolts securing the guides on the tablet press were also causing metal shavings. Bolts for the top and the bottom of where the guides were fastened were different lengths. If the opposing bolts were swapped during assembly, the incorrectly installed longer would make contact with a rotating turret that, turning at high RPMs, would shear the metal bolts.

127. By August 2012, Impax still had not corrected the presence of metal contamination above acceptable thresholds. By this time, according to CW 3, Impax had posted a regular visual display on a bulletin board in the manufacturing facility that tracked daily and weekly individual product runs with no metal contamination. The number of successful runs was "low to [Impax's] satisfaction and they wanted to improve it."

128. According to CW 3, at some point in 2011 or 2012, Impax attempted to develop a metal cleaning method that would reduce or preclude disassembling machines in order to reduce metal contamination. This effort was implemented under Paul Shrock, who was plant superintendent from July 2011 to July 2012. Yet the attempt to develop a process never came to fruition.

F. IMPAX TECHNICIANS ROUTINELY VIOLATED PROCEDURES, WHILE QA STAFF AND IMPAX EXECUTIVES RECKLESSLY FAILED TO BECOME ADEQUATELY INVOLVED IN ON-THE-GROUND SUPERVISION NECESSARY TO FIX IMPAX'S PROBLEMS

1. Technicians Pervasively Disregarded SOPs

129. During the entire time that CW 4 worked as a technician at Impax, from February 2011 to January 2012, CW 4 witnessed how fellow employees regularly ignored SOPs. In one instance, CW 4 was encouraged to stop supervising (without replacement) one of the PLA 4000 mixers – a machine that added liquid to chemicals after the weighing phase – so CW 4 could take a lunch, even though SOPs clearly required that a technician must watch the machine at all times and record intermittent data into the batch record. Similarly, on a separate occasion, CW 4 went to the restroom only to find an entire group of technicians who worked together on another process all in the restroom together – in violation of the requirement that at least two technicians were to remain in any given room at all times. "Someone should have been back at the machines." On yet another occasion, CW 4's Team Lead overrode the time that CW 4 recorded on the batch record for the PLA 4000, because the time – though accurate – was shorter than the times on previous batch records for the same process. The Team Lead required CW 4 to change the time that CW 4 had noted to a false time that more closely tracked other records. This change was against policy.

130. CW 4 also reported that more seasoned technicians led new employees to disregard SOPs, because older technicians trained new ones. More precisely, CW 4 had once been instructed to simply follow the verbal commands of CW 4's trainer and "'just do what the trainer wants because they're signing off on the process [paperwork].'" CW 4 explained that a lot of older technicians "wouldn't do [tasks] by the SOPs" because of their older habits that they believed were adequate or superior. They told CW 4, "'Oh no, we do it this way or that.'" For

instance, one of CW 4's fellow technicians regularly cleaned a machine by rinsing it in plain water, despite that the SOP clearly required a water rinse, soap scrub, and second rinse. Similarly, other technicians ignored SOPs requiring use of distilled water rather than plain water. "It was pretty common that the SOPs weren't followed. Every time there was a new [SOP] update in my department, people ignored it," said CW 4.

131. Sophie Chang, who was a manufacturing technician on the graveyard shift, also observed pervasive disregard for SOPs. Chang told CW 11, a Warehouse Supervisor with whom Chang was friendly, about how technicians were bypassing a drying machine SOP that required technicians to stay in the room with the drying machine and take notations of time intervals until the cycle was complete. Chang told CW 11 how technicians left the room during the drying cycle, which was against SOPs. "They don't follow procedures," Chang complained, adding that Impax was "one of the worst companies I've ever worked for."

132. CW 10, who was the Associate Director of HR, stated that CW 10 had to take disciplinary action against manufacturing technicians who were opening barrels of obsolete materials and using the contents of the barrels in production.

133. Finally, CW 4 stated that a fellow technician told CW 4 that he and fellow technicians had received direction about when QC and QA were set to inspect the encapsulation machine. As a result, technicians were instructed to clean the encapsulation machines especially well. According to CW 4, these internal audits were infrequent and were supposed to be secretly timed and targeted. Yet CW 4 stated that on at least one occasion the fellow technician had received "a paper that told him which parts" of the machine "would be tested and inspected" and he knew when the inspection would take place.

134. Another witness also reported that internal audits were not taken seriously at Impax. CW 9 reported that before the FDA issued a Warning Letter to Impax in May 2011, the QA Compliance department recommended to management that the company audit the R&D laboratory, because they anticipated FDA interest due to the impending NDA for and subsequent launch of Rytary. Yet, CW 9 stated that the manager of R&D, Suneel Gupta, told internal auditors that the R&D division "conduct[ed] our own audits." CW 9 stated that GMP practices did not allow a department to ***self***-audit. Eventually, Impax brought in external auditors to audit the R&D department in 2012.

135. After the FDA's issuance of the 2011 Warning Letter, CW 12, a Tooling Specialist, recounted how technicians complained about the burdensome nature of SOPs at all-employee meetings that CW 12 attended. In one particular meeting that included night shift technicians and QA staff, and which took place sometime in 2011 to 2012, CW 12 stated that employees again complained to supervising staff at the meeting of how SOPs and checklists slowed production. CW 12 recalled that Senior Production Supervisor Joe Zipko responded to the technicians' complaints by saying, "This is the way you're supposed to do it. If you think you can do it better, then so be it. But if you get caught doing it the wrong way, you'll get in trouble." In short, there was an awareness of and tacit tolerance for disregarding SOPs.

136. CW 11, a Warehouse Supervisor, stated that CW 11 expressed concerns to CW 11's superior, Ron Valine, a Warehouse Manager, about the lack of training for warehouse and manufacturing facility employees on SOPs. "They don't read the [SOP] updates," CW 11 told his manager, who did not seem to care. Instead of training employees, managers at Impax often signed off on employee training whether it had been completed or not completed. The lack of employee training occurred the entire time that CW 11 was employed at Impax; however, the

Company began training manufacturing employees just prior to CW 11's departure. But still, "they never addressed warehouse training." Shaheed Mohamed, who was another supervisor in the warehouse, severely lacked understanding of SOPs. "If there was an audit, internal or external, Shaheed was not allowed to be involved because he would fail." His sloppy training and lack of minimal familiarity with SOPs was tolerated and even covered up.

137. Moreover, warehouse employees were required to fill-out transaction documents whenever they moved raw materials. Yet CW 11 stated that employees were leaving fields on the transaction forms blank. "You cannot leave the fields blank" assured CW 11. After the March 2012 FDA inspection, CW 11 had to pull old transaction records to look for any that had blank fields, but the problem continued through 2012. CW 11 stated that a look through Impax's emails would show "emails from me to my manager about documentation [problems], and he wasn't addressing it until 2013."

138. In yet another instance of lax habits, even where paperwork appeared complete, CW 12 described a failure of QA personnel to supervise in accordance with SOPs on CW 12's tasks. For instance, CW 12 received up to 200 punches a night that he was required to inspect, and also to record verification in his inspection in paperwork. (Punches are stamps that imprint letters on pills). CW 12 would inspect the punch letters as well as the serial numbers on the machines to make sure everything was in order, and QA staff would verify his work. "Once I brought in my paperwork, they [Quality Assurance staff] were supposed to inspect each and every punch themselves. But they would never do that. They'd just glance, not inspect individual ones. Or they'd inspect a couple and say ok." Yet this superficial inspection, CW 12 explained, could allow problems to slip by: if the punch was supposed to punch a "B" but had been set to a "D" and then went into production, the pill could make it to the consumer and cause confusion.

2. Technicians and Supervisors Worked Positions for Which They Were Unqualified or Untrained

139. CW 10, Associate Director of HR, stated that "many people in operations felt that QA was not doing their job. They did not have the right people in place or documentation system in place." CW 10 further added that "Quality Assurance management was wrong, they were not good managers. May Chu started with Larry [Hsu] years ago" and, as such, gave Chu autonomy. Similarly, Jim Kou, Associate Director of Quality Control, had very high turnover rate of employees working underneath him, which amounted to opportunity losses and administrative costs.

140. Loyalty to personnel who had demonstrated problems with GMP compliance were tolerated at Impax and such personnel were allowed to stay in their positions. CW 10 gave the example of Sulaman Ahmad who, according to CW 10 and corroborated by CW 4, had problems with FDA violations and personnel management issues. CW 10 stated that Ahmad "valued affiliation over doing the job right."

141. As an example of lack of supervision, CW 4 pointed out that during CW 4's time as a technician at Impax in the weighing and labeling departments, CW 4's entire shift of employees was without a manager because the manager had been on leave for a period of 1.5 months for disciplinary reasons. Yet Impax had not hired or appointed an interim manager.

142. According to CW 6, Associate Director of Manufacturing and Associate Plant Manager, Impax "brought in countless number of people to do data mining" after the May 2011 Warning Letter. Approximately 20 new employees were assigned to conduct "retrospective batch record reviews." CW 6 could barely find space in the manufacturing facility to place new employees. CW 6 stated that the data mining was overseen by Kangwen Lin, Director of Technical Services. Yet Lin was the same individual who was the basis for the FDA's verbal

warning as described in Baker and Millar's EIR in spring 2011. FDA investigators reprimanded Lin and Impax due to Lin's having misled federal investigators about the pattern of metal contamination, calling it "grey particles" – a federal offense under Title 18, as noted in the EIR and as investigators explicitly communicated to Impax management during the inspection. According to the FDA's EIR, Lin only relented when investigator Baker showed Lin documentation that confirmed the contamination was metal. Despite this demonstrated inability to understand or accurately execute cGMP standards, Lin was also in charge of the "technical services group" which was the liaison between Research & Development ("R&D") and manufacturing. R&D was the sector of Impax that designed the processes by which drugs would later be manufactured en masse. The first type of batch records were developed in R&D during this phase, and then the technical services group would scale-up the R&D-designed batch record to accommodate manufacturing.

143. CW 7, a third-party consultant whom Impax hired to audit its R&D Lab in the summer of 2012, stated that CW 7 left Impax with a clear impression that analysts and management were not aware of the things they needed to do to be in accordance with FDA regulations. "I sensed a general lack of awareness around documentation. The analysts were not aware of the things they should be documenting. The management was not aware of the things they were supposed to be documenting."

144. CW 8, who was responsible for the development and management of technical and regulatory training as well as integrated quality compliance systems at Impax from June 2010 to January 2013, stated that "I saw a lot of movement, a lot of consultants. I didn't see any internal reports on progress."

3. Impax's Facilities Were Unequipped to Meet GMP Regulations, and Unequipped to Timely Adopt Wholesale QC Improvements and New Practices, Due to the Limitations of its Facilities, Equipment, Space, and Technology

145. CW 8 recounted that in a town hall meeting open to all employees and held at Impax shortly after the FDA Warning Letter was issued in May 2011, Defendant Hsu acknowledged that the Company was going to have to make changes to the way Impax was conducting its business. "He told us publicly that the way they were doing business was fine back in the day, but the FDA became more sophisticated." Hsu acknowledged that Impax's old way of doing things was no longer acceptable, and that Impax "need[ed] to change."

146. CW 8 stated that Defendant Hsu's public announcements of a goal to close-out the May 2011 Warning Letter by February 2012 were "not realistic based on the quality of systems that I saw." CW 8 never expected a clean inspection in any of the FDA's visits. Instead of a clean inspection, CW 8's simply wondered "just how bad it was going to be" in the FDA's reports. CW 9, a Senior Quality Assurance Compliance Associate, echoed similar expectations. CW 9 did not think that Impax would pass the 2012 inspection: "I don't think they were going to pass inspection because of the problems they were having. Not in the time frame they had in mind."

147. Indeed, it was apparent that the team of consultants could not fix limitations at Impax. CW 5 reported that manufacturing managers included in their budgets toward the end of each year room for their "needs and wants," which tended to request equipment for dust control, space for cleaning, and more automated equipment. But they never received the funding from executive management to meet those needs. Yet Impax was "a small facility that expanded very, very fast." As such, Impax did not put money into making the manufacturing facility automated. Impax's manufacturing facility was like a 1970s facility – which CW 5 would know, because

CW 5 began CW 5's career in the industry in the early 1970s: "Impax was back where I had started in 1971, scooping by hand. There was no automation." Compared to industry standards, "there was so much equipment out there they weren't using." In fact, Impax "got in trouble with the FDA" about the equipment's age. As a comparison, when CW 5 had worked for a different industry heavyweight pharmaceutical company, one technician could run two high-speed machines. Yet, by comparison, it took two or three technicians to run just one machine at Impax. Likewise, in CW 5's experience, most pharmaceutical companies had automated the recordation of validation procedures, instead of relying on manual note-taking, the latter of which increased the possibility of errors. For some of the efforts Impax spent to fix problems after negative FDA inspections, CW 5 believed that the hiring of consultants "seemed like a Band-Aid." CW 5 did not believe the consultants were effective. CW 5 was not the only witness to state that Impax relied on Band-Aid solutions: in describing Impax's practices around preparing and hosting FDA inspections (discussed above), CW 1 stated that Impax would make a temporary change to solve a problem, only to soon reverse the change. "Impax had a policy to put a Band-Aid on it temporarily," CW 1 stated.

148. In similar manner, CW 7, a consultant whom Impax hired as part of a group from Validant to audit its R&D Lab, remarked on Impax's lag behind industry standards in technology. Despite desktop computers, all lab notebooks and data were in paper form and nothing about the R&D machinery was computerized. Impax was "the least digital company I've ever seen…. I've never seen it all on paper before."

149. CW 9, who conducted internal audits as part of Impax's QA Compliance sector stated that QC Lab was no different from CW 7's experience with the R&D Lab. In an audit that consisted solely of lab notebooks, and not actual procedures, CW 9 stated that lab data was

scattered, and "nobody could make sense of it." One analyst would reference another analyst's work but there would be no way to easily find the referenced analyst's work. "Now [analysts were] just quoting them, not doing [their] own data anymore." Analysts also copied, cut, and pasted original raw data into the lab notebooks from data packets that were stored in manila envelopes, because the originals were too large to paste into the notebooks. This was "to save space, but it created more work for themselves. The witness would have to verify both, to make sure that the data was correct…. If you needed the original, you would have to pull the manila envelope." Some of the problems that CW 9's internal audit team discovered showed up in the FDA's reports. CW 9 stated that CW 9 and other auditors thought, "Well, we wrote it in the [audit] report to management. Why wasn't it fixed?" CW 9 stated that audit findings were compiled in a report in Word with Excel charts incorporated into the Word document if necessary and distributed to senior management via email, including Defendant Hsu**.** Mark Shaw, Jeff Nornhold and Mike Fitch also received the audit reports. Management provided feedback to department heads, but CW 9 was not included in those communications.

150. CW 8, who was Director of Global Training and who worked on Quality QA, stated that R&D lacked quality assurance activities. "There was not adequate science going on for quality…. When you design a product you need to understand it and put good science up front. The science wasn't there," CW 8 stated.

151. Indeed, Impax had vast and drastic improvements to make if it were going to rise to FDA standards. Senior management had knowledge, or recklessly disregarded evidence of the pervasive and severe problems at Impax, which included deviations in production as well as noncompliant record keeping. As CW 6 explained, manufacturing batch records went through a few layers of review: from the manufacturing supervisor who reviewed for completeness and

clarity, to a round of review by quality assurance, and then, when triggered by the finding of "anything unusual," to a review by the supervisory quality assurance group. In this final stage, a collection of auditors would conduct a first pass of review, and then a second group of auditors would conduct a second pass. Lastly, the Quality Assurance Supervisor would review the batch records. CW 6 further explained that Impax tracked the number of deviations from batch records and the timeliness of investigations. Notably, when a batch is under investigation, it is typically held 20 to 25 days – "the product doesn't leave the plant." According to CW 6, this delay is problematic, and the supply staff becomes stressed. Thus, even if executives attempted to ignore QC gaps, they nonetheless would inevitably become aware of the pervasive QC shortfalls by virtue of their investment in releasing product for distribution to meet sales goals. CW 6 stated that "I know for a fact that if we happened to get a deviation with a product, Jeff [Blumenfeld] would be called over to the building where exec[utive]s are and have a meeting. There were instances where Jeff was called over to Larry [Hsu] to discuss what was going on with this or that product." Outside of such *ad hoc* meetings, Blumenfeld (Senior Director of Manufacturing) regularly met in person on a weekly basis with Defendant Hsu, while Blumenfeld and Hildenbrand (VP of Operations) met even more frequently, according to CW 6.

152. CW 6 stated that Impax had replaced a "considerable amount" of quality management by CW 6's departure in February 2012. However, "whether or not you get a culture change to stick is questionable." For this reason, there was "an appropriate level of concern" at Impax, in part, because "changes may not have made it down to the rank-and-file and stuck." CW 9 echoed the same concerns: after the Warning Letter in 2011, Impax made an effort to replace a significant portion of the previous personnel and management. Despite this effort, as CW 9 explained, a lot of personnel did not understand the changes being implemented.

153. CW 8 stated that CW 8 "was in a meeting with the FDA every time they came." CW 8 stated from CW 8's own experience that, at Impax, "the quality systems weren't there." Moreover, the problems that the FDA highlighted in its investigations were "rather old," meaning that they had been going on for a long time. Indeed, "anyone [who] worked in quality knew [Impax] had some serious problems."

VIII. DEFENDANTS ISSUED FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

154. On June 6, 2011, Impax issued a press release providing an update on the FDA site inspection of the Hayward facility and its receipt of a Warning Letter. The release stated in part:

> The Company notes that the observations cited in the letter relate to the Hayward manufacturing facility only, and do not relate to any of the Company's other facilities. It also notes that until remedial action is complete and the FDA has confirmed compliance with cGMP, approval of pending and new applications listing the Hayward facility as a manufacturing location of finished dosage forms may be withheld. The warning letter did not place restrictions on the Company's ability to manufacture and ship product. While during the past three months, the production level at the Hayward facility was reduced to implement several key changes in the Company's quality system, the Company is now producing product at a normal pace and does not currently plan to reduce its product manufacturing or hold shipments of finished product.
>
> Following the initial inspection, the Company took a number of steps to thoroughly review its manufacturing systems and standards, including the use of leading consulting firms to assist in that review. This work is ongoing and the Company is committed to improving its manufacturing practices. The Company will continue to work to fully address the FDA's concerns and to resolve these issues. The Company will respond to the FDA's warning letter within the mandated 15 business day response period.

In particular, the press release quoted CEO Hsu:

> "Impax remains committed to providing the highest quality products to our customers and working with the FDA to diligently resolve any issues…. ***We intend to promptly respond to the FDA's letter, and have already begun to implement changes and establish procedures that address the observations cited during the inspection. We will work diligently to remedy any outstanding issues in a timely manner***…. We don't anticipate that this manufacturing setback will delay our ongoing

> research and development activities. We expect to continue to develop our generic pipeline of 82 products and two brand products."
>
> (Emphasis added.)

155. The statements in Paragraph 154, above, concerning the Warning Letter from the FDA and the remediation measures that would be implemented to rectify the deficiencies cited therein including the statements about the "changes" and "procedures" that were or would be implemented and that the Company would work to implement the changes in a "timely manner" were each materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed, would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the Observations of GMP deficiencies as cited in the Warning Letter because: (a) Impax had a practice and culture of implementing and reversing corrective measures as a temporary solution to pass FDA onsite inspections (*see* ¶¶ 102-109, above); (b) Impax had a demonstrated history of problems with cleanliness and sanitation exacerbated by its lack of space for its operations, the failure to stop production when insects were found or as required when certain machinery malfunctioned, and technicians chronically disregarded SOPs pertinent to cleaning (*see* ¶¶ 110-114, 130, 147, above); (c) Impax employees did not observe proper cGMP practices regarding documentation and maintenance of accurate batch records because technicians pre-filled or wholesale completed batch records rather than doing so step-by-step, employees in the laboratory maintained a convoluted and confusing system to record raw data, and technicians or audit teams failed to fully investigate and document deviations in production (*see* ¶¶ 52, 69-72, 99, 115-123, above); (d) Impax had antiquated machinery that was in chronic disrepair, and even where some machinery was in acceptable condition, it was too old to sufficiently execute production tasks sufficient to meet cGMP

requirements (*see* ¶¶ 78-80, 82, 84, 124, above); (e) Impax had continually failed to locate all root causes of metal contamination and the "black specks" contamination in other tablets (*see* ¶¶ 66, 73-74, 81, 90-91, 125-128, above); (f) Impax employees rampantly disregarded SOPs and trained new staff to disregard SOPs, while supervising staff tacitly tolerated deviations from SOPs and other supervising staff did not maintain adequate knowledge of the latest updated SOPs (*see* ¶¶ 114, 100, 129-138, above); (g) both before and after the Class Period, as noted by CWs and in the 2013 Form 483, Impax repeatedly appointed or failed to remove employees who were or became unqualified or untrained for their positions (*see* ¶¶ 100, 139-144, above); (h) both before and after the Class Period, Impax facilities were generally inadequate because they lacked sufficient space to avoid storing products incorrectly in the hallways or non-conforming warehouses, equipment was lacking or technologically insufficient to support proper cGMP practices (*see* ¶¶ 102-104, 107, 147-150, above); and (i) both before and after the Class Period, as noted by CWs and ***all five*** Form 483s as well as the Warning Letter, Impax failed to fully investigate and document deviations in manufacturing (*see* ¶¶ 52, 99, 117-118, 120, above).

156. In an earnings call on August 2, 2011, Hsu informed investors that Impax's remedial measures implemented in response to the FDA's warning letter were nearing completion, stating "Many commitments in our responses ***are nearing completion*** as a result of our work since we received the Form 4[8]3…. ***We hope to be able to close out the warning letter in the next six to eight months***." (Emphasis added).

157. The statements in Paragraph 156, above, concerning the Warning Letter from the FDA and the remediation measures that would be implemented to rectify the deficiencies cited therein including the statements about the "commitments" that would be implemented in response to the Warning Letter were "nearing completion" and that Impax hoped to resolve the Warning

Letter in "six to eight months" were each materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed, would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the Observations of GMP deficiencies as cited in the Warning Letter due to reasons (b) through (i), listed above in Paragraph 155, above, as well as an additional reason (j) that Impax had no basis to set a short end date or timely resolution of the Warning Letter because: many of its pervasive deficiencies had been ongoing problems for years and (k) because Impax had not even finished supplementing its initial response to the Warning Letter, which it would do by letter on September 9, 2011 (*see* ¶¶ 90-91, above).

158. Also on August 2, 2011, Impax issued a press release announcing its second quarter 2011 financial results. The release quoted CEO Hsu as stating in part:

> We are working expeditiously to resolve the manufacturing observations raised in the warning letter to the satisfaction of the U.S. Food and Drug Administration (FDA). In late June 2011, we submitted our warning letter response and will continue to cooperate with the FDA to resolve the observations. ***We have already made significant manufacturing and quality control systems improvements and believe we have addressed a number of the FDA's observations.*** Upon our internal completion, we will request a re-inspection of our Hayward facility by the FDA, the timing of which is wholly dependent upon the FDA's availability. Based on our most recent estimate, we expect to incur charges of approximately $10.0 million in 2011 related to the development and implementation of manufacturing and quality control systems improvements associated with our response to the observations raised in the warning letter.
>
> (Emphasis added.)

159. The statements in Paragraph 158, above, concerning the Warning Letter from the FDA and the remediation measures that would be implemented to rectify the deficiencies cited therein including the statements about the "improvements" that had "already" been "made" and Impax's belief that it had already addressed "a number" of deficiencies cited by the FDA were

each materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed, would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the Observations of GMP deficiencies as cited in the Warning Letter due to reasons (b) through (j), listed above in Paragraph 155, above.

160. Impax's Form 10-Q issued for the quarterly report ending on June 30, 2011, and signed on August 4, 2011 by defendants Hsu and Koch, stated that Impax had received a Warning Letter from the FDA. In response, Impax assured investors that:

> We have taken a number of steps to thoroughly review our quality control and manufacturing systems and standards and are working with several third-party experts to assist us with our review…. ***[W]e have made significant quality improvements and are working to complete the material elements of our internal work as quickly as possible.*** Upon the completion of our internal work, we will request a FDA re-inspection of our Hayward, California manufacturing facility, with the goal of being able to close out the observations to FDA's satisfaction by the early part of first quarter 2012.
>
> (Emphasis added.)

161. The statements in Paragraph 160, above, concerning the Warning Letter from the FDA and the remediation measures that would be implemented to rectify the deficiencies cited therein including the statements about the "significant quality improvements" that had been "made" and Impax's timely completion of "material improvements" were each materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed, would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the Observations of GMP deficiencies as cited in the Warning Letter due to reasons (b) through (j), listed above in Paragraph 155, above.

162. In an earnings call on November 1, 2011, Koch stated with respect to clearing the Warning Letter:

> [W]here we are now is on track, and, therefore, ***I think investors can be comfortable that we're where we need to be*** and we expect to hit that target [of the February 2012 deadline].
>
> (Emphasis added.)

163. The statements in Paragraph 162, above, concerning the Warning Letter from the FDA and the remediation measures that would be implemented to rectify the deficiencies cited therein including the statements that Impax's progress was where it "need[ed] to be" and that Impax "expect[ed] to hit" the deadline of February 2012 to resolve the Warning Letter were each materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed, would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the Observations of GMP deficiencies as cited in the Warning Letter due to reasons (b) through (j), listed above in Paragraph 155, above, and because (l) Impax had received a letter dated October 4, 2011 from the FDA signaling to Impax that, despite its several letters to the FDA supplementing Impax's responses to the Warning Letter, they were not complete because the FDA needed further clarification before proceeding (*see* ¶ 91, above).

164. In Impax's Form 10-Q, signed by Defendants Hsu and Koch, issued for the quarterly report ending on September 30, 2011 and filed on November 3, 2011, Impax made near verbatim assurances about its timeline for closing out the Warning Letter, but this time set a target end-date for investors stating that:

> We have ***made significant quality improvements*** and are working to complete the material elements of our efforts as quickly as possible ***with the goal of being able to close out the warning letter by the end of February 2012***. However, FDA re-inspection is required to close out the warning letter, the timing of the re-inspection is wholly dependent upon

> FDA's availability, and we cannot assure the FDA will be satisfied with our responses and corrective actions and/or will not identify additional observations upon their re-inspection. Unless and until our corrective ***action*** is completed to the FDA's satisfaction, it is possible we may be subject to additional regulatory action by the FDA as a result of the current or future FDA observations….
>
> (Emphasis added.)

165. The statements in Paragraph 164, above, concerning the Warning Letter from the FDA and the remediation measures that would be implemented to rectify the deficiencies cited therein including the statements how Impax had "made" "significant" remedial measures and could reasonably maintain a "goal" to close out the Warning Letter by February 2012 were each materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed, would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the Observations of GMP deficiencies as cited in the Warning Letter due to reasons (b) through (l), listed above in Paragraph 163, above.

166. At the Credit Suisse Group Health Care Conference held on November 11, 2011, Impax made further assurances about its progress on the resolution of issues resulting in the May 2011 Warning Letter. In particular, Koch stated:

> With so much of our future and our value in our pipelines, we cannot tolerate meaningful deviations from cGMP such as those outlined in the letter. We have made a ***commitment to quality that is evidenced in many ways beyond our response to the FDA's letter***, including we have begun to upgrade our management and our systems so that future inspections as well as the necessary re-inspection go well. The agency frequently cites that a firm's quality standards emanate from the top and we have developed a very simple clear message. ***We will comply, we will stay abreast of developments in our industry*** and we will remain compliant as we build our business. The tasks necessary to address the three issues raised in the letter are well underway and an even greater effort to upgrade our global quality system was initiated at the direction of our new leadership ***in both quality and manufacturing***…. ***[w]e believe we can close out the warning letter before March 1, 2012***, in time to preserve our

> first-to-file exclusivity on Trilipix, our next pipeline product. Of course this estimate depends heavily on the timing of the FDA's review….
>
> (Emphasis added.)

167. The statements in Paragraph 166, above, concerning the Warning Letter from the FDA and the remediation measures that would be implemented to rectify the deficiencies cited therein including the statements how Impax had "made" a "commitment to quality" and "will stay abreast" of relevant "developments" in the drug manufacturing industry and that Impax had a basis to reasonably set a goal date to close out the Warning Letter by March 2012 were each materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed, would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the Observations of GMP deficiencies as cited in the Warning Letter due to reasons (a) through (j), listed in Paragraph 155, above, and reason (l) listed in Paragraph 163, above, and because (m) Impax had not made a commitment to quality by exercising a reasonable effort to stay abreast of developments in the industry as evidenced later by CEO Hsu's statement (discussed below) on September 20, 2012 that Impax did not know the FDA – in the last ***three to four years*** prior – had come to "crack down" on a testing method that had been in use for years (*see* ¶ 176, below).

168. During an earnings call on February 28, 2012 and in reference to the May 2011 Warning Letter, Hsu stated:

> "As we pointed out in the past that we cannot adjust on the timing [on a reinspection from the FDA], but from our end ***we have done everything we can including the mock inspections and everything. So we're pretty confident at this point we will be able to handle this FDA inspection smoothly."***
>
> (Emphasis added.)

169. The statements in Paragraph 168, above, concerning the Warning Letter from the FDA and the remediation measures that would be implemented to rectify the deficiencies cited therein including the statements how Impax had "done everything" it could have, and its confidence it would "handle" the FDA reinspection "smoothly" were each materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed, would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the Observations of GMP deficiencies as cited in the Warning Letter due to reasons (a) through (j), listed in Paragraph 155 above, and because (n) Impax had failed to remedy both the employment of unqualified or untrained technicians, as well as its chronic failure to fully investigate deviations because both of these particular deficiencies existed prior to the Warning Letter and were both cited explicitly in the 2013 Form 483 as ongoing deficiencies in cGMP practices (*see* ¶¶ 52, 99-100, 117-118, 136, 139-144).

170. On May 1, 2012, in its earnings call, Impax announced receipt of the 2012 Form 483 while stressing that the 2012 Form 483 cleared its problems from the 2011 Warning Letter by virtue of the latest Form 483 only noting new and previously unobserved compliance deficiencies. During this call, Hsu stated:

> Even though the recent FDA inspection had no repeat deficiencies or observations from those cited in the 2011 warning letter, we are disappointed to have a ***new [F]orm 483 related to our quality control laboratory***. We have responded to the FDA on the items mentioned in this 483 and will continue to work as quickly as possible to resolve these items…. It remains the top priority throughout the company….
>
> [W]e will continue to devote every available resource in order to achieve and maintain FDA compliance. This ***temporary roadblock*** has not prevented us from continuing to manufacture…[o]ur pending generic pipeline of 47 products continues to expand with the filing of new ANDAs, while our brand business continues this work on pre-launch activities in anticipation of approval of RY[T]ARY….

> [A]t this point, [the] FDA has conducted the reinspection in connection to the [May 2011] warning letter and as of today we're not aware of any outstanding issue left on that.
>
> (Emphasis added.)

171. The statements in Paragraph 170, above, concerning the Warning Letter from the FDA and the remediation measures that would be implemented to rectify the deficiencies cited therein including the statements that the 2012 Form 483 related only to the QC Laboratory and that the Warning Letter was a "temporary roadblock" were each materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed, would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the Observations of GMP deficiencies as cited in the Warning Letter, which continued to remain unresolved, due to reasons (a) through (j), listed in Paragraph 155, above, and because (o) the 2012 Form 483 contained Observations relevant to manufacturing practices; deficiencies cited in the 2012 Form 483 had already been cited in prior Form 483s; and the 2012 Form 483 did not solely include Observations relevant to the QC Lab only (*see* ¶¶ 52, 95-96, above).

172. On May 16, 2012, at the Bank of America Merrill Lynch Health Care Conference, Hsu and Koch gave further assurances to investors. Koch stated that "we're very confident that we'll be able to deal with all of the issues we face and resolve this current report as quickly as possible." Hsu who also attended the conference with Koch, added, "While we don't know the exact the timing on that, but [*sic*] we have a real confidence that we will get the issue resolved."

173. The statements in Paragraph 172, above, concerning the Warning Letter from the FDA and the remediation measures that would be implemented to rectify the deficiencies cited therein including the statements that Impax was "very confident" in resolving the Warning Letter

"as quickly as possible" were each materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed, would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the Observations of GMP deficiencies as cited in the Warning Letter due to reasons (a) through (j), listed in Paragraph 155, above.

174. At the June 7, 2012 Goldman Sachs Global Healthcare Conference, Impax again stressed that the 2011 Form 483 exclusively related to manufacturing while the 2012 Form 483 related exclusively to the QC Lab. In this effort, Koch stated that the FDA:

> completed the re-inspection. The[] [FDA] went on to do a full cGMP inspection. They went into the QC lab, that's the last stop before the product is distributed, and observed these additional items. It's important to understand, ***there were no repeat observations***, so that's ***a way to be satisfied that the items included under the original warning letter are resolved to the satisfaction of the agency***…..[The new cited violations are] in the QC lab and that is – that only – they [the FDA] ***only get to that spot if they're satisfied with what's going on in manufacturing***. It's only a policy and procedures kind of comment and issue. We were able to revise the policies and procedures before the inspectors left the office. So, it's a very easy thing to address. Now we [are] working with them on their remaining questions as to our existing product.
>
> (Emphasis added.)

175. The statements in Paragraph 174, above, concerning the Warning Letter from the FDA and the remediation measures that would be implemented to rectify the deficiencies cited therein including the statements that investors had "a way to be satisfied" that the Warning Letter observations were "resolved" to the FDA's "satisfaction" and that the FDA was "satisfied" with all practices the FDA observed in "manufacturing" during the inspection were each materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed,

would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the Observations of GMP deficiencies as cited in the Warning Letter due to reasons (a) through (j), listed in Paragraph 155, above, reason (n) in Paragraph 169, above, and reason (o) in Paragraph 171, above.

176. At the UBS Global Life Sciences Conference that took place on September 20, 2012, Impax again stated that the 2012 Form 483 predominantly targeted quality control issues rather than issues relating to Impax's manufacturing. Hsu stated:

> When the inspection – re-inspection occurred in February and March, the inspector looked at the manufacturing areas, ***and there was no question no outstanding issue at all***. ***They were pretty happy with what they have seen.*** However, they did look at the QC lab, when the[y] look[ed] at it they found some problem[s], procedure problem[s]. It's called trial injection…. Now, as a matter of fact, many company[ies] ha[ve] been doing the trial injection in the QC lab for many years without any question. But for the last three years, four years, I think the FDA has cracked down on that. Obviously, we were not updated to know that. So end up with kind of clarity or a bit [*sic*]. From [the] FDA point of view, we're violating the GMP. And, as a result of that, we got a 483.
>
> (Emphasis added.)

177. The statements in Paragraph 176, above, concerning the Warning Letter from the FDA and the remediation measures that would be implemented to rectify the deficiencies cited therein including the statements that there was "no question" in the inspection and "no outstanding issues at all" and that the FDA was "pretty happy" and that the 2012 483 was simply the "result" of "trial injection" methods falling out of favor with the FDA were each materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed, would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the Observations of GMP deficiencies as cited in the Warning Letter due to

reasons (a) through (j), listed in Paragraph 155, above, reason (n) in Paragraph 169, above, reason (m) in Paragraph 167, above, and reason (o) in Paragraph 171, above.

178. In its earnings call October 30, 2012, Impax again reassured investors that it was ready for an FDA inspection. Hsu insisted:

> But at this point, as I pointed out earlier, ***we're confident we'll get out of here***, although timing, unfortunately, is not in our control, as we're waiting for [the] FDA to take the action on that. But I think we feel well prepared for this.
>
> (Emphasis added.)

179. The statements in Paragraph 178, above, concerning the Warning Letter from the FDA and the remediation measures that would be implemented to rectify the deficiencies cited therein including the statements that Impax was "confident" it would "get out" of the Warning Letter were each materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed, would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the Observations of GMP deficiencies as cited in the Warning Letter due to reasons (a) through (j), listed in Paragraph 155, above, reason (n) in Paragraph 169, above, and reason (o) in Paragraph 171, above.

IX. THE TRUTH EMERGES AS IMPAX RECEIVES THE 2013 FORM 483 WITH REPEAT OBSERVATIONS

180. On March 4, 2013, Impax stunned the market when it issued a press release in which it informed investors that after the latest re-inspection by the FDA, which included (1) a re-inspection for the Warning Letter, (2) a pre-approval inspection for Rytary, and (3) a general GMP inspection, "the FDA issued a new Form 483 with twelve observations, three of which are designated as "repeat observations" that occurred prior to the Warning Letter."

181. As explained above, FDA investigators may (and are thus not required to) indicate on a Form 483 when their observation of a significant GMP deficiency is a repeat observation from a prior Form 483 because it is an "observation made during a prior inspection [that] has not been corrected or is a recurring observation." Operations Manual 5.2.3. This indication by an FDA investigator has a heightened significance and may increase the likelihood of negative FDA action. At a minimum, the notation of a "repeat observation" demonstrates Impax's inability to remedy a serious objectionable condition that the FDA previously and expressly called to Defendants' attention. Impax's 2011 Form 483 had one repeat observation that contributed to the issuance of a Warning Letter, placing Impax on notice of the seriousness and pervasiveness of its GMP compliance. Then, two years later, the 2013 Form 483 confirmed that Impax had not remedied an important Observation from the Warning Letter. Indeed, Impax's consistent failure to fully investigate deviations, an Observation present in some form in every prior Form 483, remained uncorrected. Moreover, the 2013 Form 483 had two additional formally-marked "repeat observations" from the 2011 Form 483. The contents of the 2013 Form 483 thus confirmed what Impax executives had known all along: that Impax's problems were pervasive, severe, and intractable.

182. That same day on a call with investors, Hsu stated that "[u]nfortunately, [the] FDA standard is [] much higher today versus a few years ago…." When unable to avoid an analyst's pointed question, Hsu responded that "again, everyone knows to fix the quality it takes time." Hsu claimed that after nearly two years of Impax being under the specter of the Warning Letter that attempting to address those issues "took a big toll on our resources." Hsu also admitted that he and Impax had finally learned their lesson in dealing with the FDA. Hsu admitted that: "So I think from that point of view, we now learned the lesson that this in no longer [sic] internal

program. We're going to have to really work with the FDA, keep them posted on the progress and we're going to have to get there as many consultants as we can to help on this whole thing which we are doing now, okay? And so, my thinking is that it does have the increased urgency significantly on this internal program." These concessions were drastically inconsistent with Defendants' assurances during the Class Period that the May 2011 Warning Letter was a "temporary" interruption, and that Impax had the capability and expertise to address the FDA's concerns and that, as a result, they had a reasonable basis to believe that they were "confident" that Impax was on track to promptly resolve both Form 483 Observations as well as the significant issues raised in the Warning Letter.

183. Analysts were no longer willing to accept Defendants repeated assurances that Impax was capable of addressing the FDA's concerns and achieving a successful closure to the Warning Letter. For example, during a March 4, 2013 conference call with analysts Piper Jaffrey analyst David Amsellem noted to Hsu that "…in the context of getting the warning letter in 2011 and then having two years in a row of inspections that failed to resolve the issue….would you entertain a sale of the company?" Likewise, JPMorgan analyst Dewey Steadman characterized Impax's failures set forth the 2013 Form 483 as "based on employee compliance of GMP 101." Elliot Wilbur of Needhan and Company stated that "[i]t almost seems like you guys keep studying for the wrong exam"….and that the 2013 Form 483 is "***obviously very indicative of some systemic issue***." Finally, analyst Ken Caccitore of Cowen & Company could not hold back on noting the disconnect between the reality that was disclosed and what Defendants were leading the market to believe during the Class Period that Impax was capable of timely resolving its issues with the FDA and that it had the needed resources and expertise to do so. Caccitore told Hsu "….I think there is a disconnect between what you all are doing and what our expectations

are. We would've expected you were putting maximal effort that, the program was going as fast as possible, that you would have hired as many consultants as you possibly would have needed. So it seems from an outsider these things don't make a ton of sense why you keep on getting a lot of questions around it."

184. The market reacted immediately and severely to Impax's disclosure. On March 5, 2013, the price of Impax common stock plunged from $20 per share to close at $14.80 per share, with the Company losing approximately 26% of market capitalizationa single day of trading on exceptionally high volume of over 11,696,547 shares, ***eighteen times*** (*i.e.* 1,800%) the average daily volume for the Class Period. During the Class Period Impax common stock had traded as high as $27.02 per share.

185. On March 6, 2013, Impax gave a presentation as part of the Cowen & Company Healthcare Conference. During that call, and in response to an analyst's question, Hsu stated that, "one of the important thing[s] we learned in the last two years is quality improvement is a continuing process. ***It's not something you can put a lot of money and resources and get it done in one year***, and then say we're done with the business." (Emphasis added.) This admission was in stark contrast to Impax's initial assurances that they would clear their Warning Letter in twelve to eighteen months from its date of issuance in May 2011.

186. Likewise, on May 1, 2013, during Impax's Q1 earnings call, Hsu elaborated further on the long time table required to implement significant quality improvement. Separate from remedial measures earmarked in response to the 2013 Form 483, Hsu spoke of Impax's quality improvement program ("QIP") that it had initiated "about a year and half ago" to improve Impax's general quality control deficiencies. Hsu told analysts that: "it takes time, the QIP can take ***two, three years*** to get implement[ed] on those [changes], okay." (Emphasis added.) Later

in the call, Hsu added that the FDA issued the latest Form 483 "in the middle" of Impax's implementation of its QIP, which was a sign that "We're not there yet, but we're moving in the right direction." Later in May 2013, the Company announced that it had established a Compliance Committee composed of three independent directors to provide oversight for all activities relation to the Warning Letter.

X. LOSS CAUSATION

187. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false or misleading statements about Impax's the status of its actions to resolve the Warning Letter, as well as its capacity to do so. These material misstatements and omissions had the cause and effect of creating in the market an unrealistically positive assessment of Impax, its compliance with cGMP practices and FDA regulations, and likewise its business, prospects and operations, thus causing the Company's common stock to be overvalued and artificially inflated at all relevant times. As a result, Lead Plaintiff and members of the Class purchased Impax securities at artificially-inflated prices and were damaged when the artificial inflation gradually dissipated when a series of corrective disclosures.

188. When the true facts about the Company were revealed to the market, namely that Impax had not resolved issues critical to the close-out of the Warning Letter and had in fact failed to resolve three specific "repeat observations" that had persisted for two to three years and prior to receipt of the Warning Letter, inflation in the price of Impax stock was removed and the price of Impax stock declined dramatically causing loss to Lead Plaintiffs and the other members of the Class.

189. At about 2 p.m. on June 6, 2011, Impax filed a Form 8-K with the SEC in which it revealed that it had received a Warning Letter from the FDA. The market immediately reacted to

this news and the price per share for Impax stock dropped $2.65 from a closing price of $25.65 on June 5th to a closing price of $23.29 on June 6th on a trading volume of 1,996,156 shares, over three times the average daily volume for the Class Period.

190. At just after 9:00 a.m. EST on May 1, 2012, Impax filed an 8-K with the SEC announcing that it again received a Form 483 from the FDA (which it had actually received a month prior on March 28, 2012). The market immediately reacted to this news, and the price of Impax's stock dropped $2.01 from its April 30th closing price of $24.63 to a closing price of $22.62 on May 1st at a high trading volume of 1,148,253 shares, nearly twice the average daily volume for the Class Period.

191. On March 4, 2013 at about 4:05 p.m. EST, Impax issued a press release through BusinessWire informing investors that it had received another Form 483 – this time containing three "repeat observations" – and further announced that the Company would hold a conference call and webcast at 5:00 p.m. EST. Minutes later, Impax filed a form 8-K with the SEC at 4:13 p.m. EST that provided a redacted version of the Form 483. The Form 483 disclosed that Impax had not resolved the Warning Letter because: the cGMP deficiencies listed therein included three that were labeled "repeat observations," meaning they were deemed in the FDA inspectors' judgment to have remained uncorrected. These deficiencies had therefore persisted for two and three years since the 2010 and 2011 Form 483s in which they were first cited. In short, Impax's numerous Class Period statements about various and significant remedial measures it had already implemented to improve its companywide QC practices and to resolve the Warning Letter in a timely manner were false and misleading because, as Impax informed the market, the FDA found that these remedial measures had not been done or were unsuccessful as demonstrated by Impax's failure to correct chronic deficiencies that pre-dated the Warning Letter. Moreover,

the 2013 Form 483 contained a "repeat observation" from the Warning Letter itself, and was an explicit disclosure that conditions underlying the Warning Letter had not, in fact, been remedied. The next day, the market reacted to Impax's news and its stock plummeted $5.20 per share to close at $14.80 on March 5, 2013, at a trading volume of 11,696,547 shares – ***eighteen times*** (*i.e.* 1,800%) the average daily volume for the Class Period.

192. Had Lead Plaintiff and the Class known of the material adverse information alleged herein, they would not have purchased Impax common stock at artificially inflated prices and they would not have proximately suffered losses as the previously-withheld information became revealed to the market.

XI. SCIENTER

193. During the Class Period, Defendants had both the motive and opportunity to commit fraud. As alleged above, they also had actual knowledge of the misleading nature of the statements they made or acted with deliberate recklessness with regard to the true information known to them at the time for the reasons discussed above. In so doing, Defendants committed acts, and practiced and participated in a course of business that operated as a fraud or deceit on purchasers of Impax common stock during the Class Period.

194. Impax and the Individual Defendants knew or recklessly disregarded the extent and degree of pervasive GMP deficiencies at Impax. Defendants were placed on notice of these problems due the FDA's explicit in-person explanations during exit interviews of the five Form 483s issued from 2009 to 2013, as well as in the FDA's numerous correspondence addressed to CEO Hsu as well as other executive management. Moreover, as explained above, Defendants had actual knowledge of these egregious QC deficiencies due to various interactions with managerial

staff, including meetings with Jeff Blumenfeld when product was delayed due to batch record deviations.

195. The issues cited in the Form 483s as well as the 2011 Warning Letter were critical to Impax's business, because resolution of the Warning Letter was necessary for Impax to receive clearance on numerous pending ANDAs as well as the NDA for Rytary. By the spring of 2013, Impax had not received approval on any ANDA or NDA in nearly ***two years*** due to issues highlighted not only in the Warning Letter, but as more fully explored in the back-and-forth correspondence with the FDA by letter and telephone from June 2011 through and including January 2012. Accordingly, the Individual Defendants had a strong incentive to familiarize themselves with the true nature of Impax's profound quality control and manufacturing problems that were the subject of repeated FDA observations and the Warning letter.

196. Individual Defendants further had motivation to mislead investors due to their substantial holdings in Impax common stock and their substantial compensation. At the end of the class period on March 4, 2013, Hsu directly owned 621,060 shares of Impax common stock, and indirectly owned over 2.3 million shares of Impax common stock via the Hsu Family trust, with another 151,213 shares of Impax common stock indirectly owned through his spouse. Koch left Impax on June 29, 2012, and his most recent filing with the SEC on May 30, 2012 stated that Koch owned 142,415 shares of Impax common stock. In addition, CEO Hsu's compensation for FY 2012 totaled $3,381,078; and CFO Koch, who left Impax during 2012, had a total compensation for FY 2011 of $1,654,082. Individual Defendants had reason to conceal from the market the difficulties in resolving the Warning Letter as well as the nature and severity of Observations in subsequent Form 483s to protect their substantial financial investments in both Impax and their executive positions.

197. As detailed above, Defendants were aware of these material adverse facts during the Class Period because critically deficient GMP practices were egregious, pervasive, and widely known at Impax. Notably, the 2009, 2010, and 2011 Form 483s reinforced the seriousness of the Warning Letter, which itself contained repeat observations first cited in both the 2010 and 2011 Form 483s. Both the repetition of the observations, as well as their elevation to the status of a Warning Letter, placed executives on notice that GMP practices were pervasively and consistently deficient and therefore required affirmative investigation and understanding on the part of the Company's top executives, and rendering any lack of familiarity with the actual conditions of GMP practices – at a minimum – deliberately reckless. Additionally, QC employees regularly audited manufacturing batch records for deviations. If reports detailing batch record deviations were not directly consulted by management, management would inevitably become aware of QC problems in manufacturing because product batches held for resolution of QC deviations would seriously impact sales and customer relations and thus trigger executive review. CW 6 stated that "I know for a fact that if we happened to get a deviation with a product, Jeff [Blumenfeld] would be called over to the building where exec[utive]s are and have a meeting. There were instances where Jeff was called over to Larry [Hsu] to discuss what was going on" with particular products when problems arose.

198. Outside of such *ad hoc* meetings, Blumenfeld (Senior Director of Manufacturing) regularly met in person on a weekly basis with CEO Hsu, while Blumenfeld and Hildenbrand (VP of Operations) met even more frequently, according to CW 6. Similarly, CW 10 stated that Impax had regular weekly staff meetings, which were often located in the conference room next to Hsu's office, that heads of department attended to discuss important performance issues. These meetings included the attendance of Charles Hildenbrand (Senior VP of Operations until

June 2011), Jeff Blumenfeld (Senior Director of Manufacturing), Kangwen Lin (Director of Technical Services), Larry Glenn (Director of Operations in Philadelphia, attending by phone), Dave Huettig (VP of Engineering), and Joe Camargo (VP of Manufacturing & Materials Management/VP of Supply Chain). CW 10 also stated that Impax staff held monthly Continuous Improvement meetings that Hildenbrand had started in September 2007, and included the attendance of May Chu (VP of Quality Assurance), Camargo, Huettig, Robert Bertolani (VP of Quality Systems Assurance), Jim Kou (Associate Director of Quality Control), Ray Jahn (Dir. of Maintenance Engineering), Lin, and Rosie Sison (Sr. Manager of Commercial QA). Finally, the 2011 Form 483 had one official "repeat observation" that persisted from the 2010 Form 483 issued to Impax and thus placed executives on notice that deeper investigations and more stringent remedial measures were required in response to the 2011 Form 483.

XII. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR

199. The statutory safe harbor applicable to forward-looking statements under certain circumstances does not apply to any of the false and misleading statements pled in this Complaint. None of the misstatements and omissions complained of herein was a forward-looking statement. Rather, the false or misleading statements and omissions complained of in this Complaint concerned omissions of historical and/or current facts and conditions existing at the time the statements were made.

200. Alternatively, to the extent that any of the false or misleading statements alleged herein can be construed as forward-looking statements, they were not accompanied by any meaningful cautionary identifying important facts that could cause actual results to differ materially from those in the purportedly forward-looking statements. Impax provided only general disclosures that were not meaningful in light of the information they omitted to disclose

concerning the nature and impact of the FDA inspections and Form 483s, as well as the May 2011 Warning Letter. Alternatively, to the extent the statutory safe harbor would otherwise apply to any forward-looking statements pleaded herein, the Defendants are liable under the Exchange Act for those false or misleading forward-looking statements because at the time those statements were made, the speaker(s) knew the statement was false or misleading, or the statement was authorized and/or approved by an executive officer of Impax who knew that the statement was materially false or misleading when made.

XIII. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE

201. Plaintiffs are entitled to a presumption of reliance under *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because claims asserted herein against Defendants are predicated in part upon material omissions of fact that Defendants had a duty to disclose.

202. In the alternative, Plaintiffs are entitled to a presumption of reliance on Defendants' material misrepresentations and omissions pursuant to the fraud-on-the-market doctrine because, at all relevant times, the market for Impax securities was open, efficient and well-developed for the following reasons, among others:

(i) The market for Impax securities was, at all relevant times, an efficient market that promptly digested current information with respect to the Company from all reliable, publicly-available sources and reflected such information in the price of Impax securities;

(ii) Impax common stock met the requirements for listing and were listed and actively traded on the NASDAQ, a highly efficient and automated market;

(iii) The Company was consistently followed, before and throughout the Class Period, by the media, which issued numerous news stories regarding Impax during the Class Period. Impax was followed by numerous securities analysts employed by firms including Wells Fargo Securities, LLC; Thomson Reuters; Piper Jaffray; Guggenheim Securities, LLC; Wright Investors Service; Marketline; Buckingham Research Group, Inc.; JPMorgan; RBC Capital Markets; Canaccord Genuity Jeffries & Co., Inc.; Leerink Swann; Sadif-Investment Analytics SA; Cowan and

Company; Summer Street Research; and ThinkEquity LLC, among others, who wrote reports about the Company and the value of its securities that were publicly available and entered the public marketplace. Indeed, there was extensive securities analyst coverage of Impax, with approximately 400 analyst reports published during the Class Period from June 6, 2011 through March 4, 2013;

(iv) The price of Impax common stock reacted promptly to the dissemination of new information regarding the Company, as set forth above. Impax securities were actively traded throughout the Class Period, with substantial trading volume and average weekly turnover and high institutional investor participation. The average daily trading volume for Impax common stock during the Class Period was 640,652 shares;

(v) Impax regularly communicated with public investors through established market communication mechanisms, including through regular press releases, which were carried by national and international news wires, and through other wide ranging public disclosures, such as communications and conferences with investors, the financial press and other similar reporting services; and

(vi) As a public company, Impax filed period public reports with the SEC.

203. As a result of the foregoing, the market for Impax common stock promptly digested current information regarding Impax from all reliable, publicly available sources and reflected such information in the price of Impax's securities. Under these circumstances, purchasers of Impax securities during the Class Period suffered injury through their purchase of Impax securities at artificially-inflated prices and a presumption of reliance applies.

204. Accordingly, Lead Plaintiff and other members of the Class did rely and are entitled to have relied upon the integrity of the market price for Impax securities and to a presumption of reliance on Defendants' materially false and misleading statements and omissions during the Class Period. Additionally, Lead Plaintiff is entitled to a presumption of reliance because the claims asserted herein against Defendants are also predicated upon omissions of material fact which there was a duty to disclose.

XIV. CLASS ACTION ALLEGATIONS

205. Lead Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all those who purchased the common stock of Impax during the Class Period and who were damaged thereby (the "Class"). Excluded from the Class are Defendants; the officers and directors of the Company, at all relevant times; members of their immediate families; and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

206. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Impax shares were actively traded on the NASDAQ. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Impax or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

207. Lead Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

208. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

209. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Impax;

(c) whether the Individual Defendants are personally liable for the alleged misrepresentations or omissions described herein; and

(d) to what extent the members of the Class have sustained damages and the proper measure of damages.

210. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

211. Lead Plaintiff incorporates ¶¶ 1-200 by reference.

212. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and/or failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) employed devices, schemes, and artifices to defraud;

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Lead Plaintiff and others similarly situated in connection with their purchases of Impax common stock during the Class Period.

213. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false or misleading statements about Impax's ability to correct deficient practices and cure observations as noted both in the five Form 483s issued from 2009 to 2013 as well as the Warning Letter that the FDA issued in May 2011. These material misstatements and omissions had the cause and effect of creating in the market an unrealistically positive assessment of Impax and its business, prospects and operations, thus causing the Company's common stock to be overvalued and artificially inflated at all relevant times. When the true facts about the Company were revealed to the market, namely that Impax was incapable of resolving deficiencies cited in the May 2011 Warning Letter, inflation in the price of Impax stock was removed and the price of Impax stock declined dramatically causing loss to Lead Plaintiff and the other members of the Class.

214. Thus, at all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Lead Plaintiffs and other members of the Class.

COUNT II

Violation of Section 20(a) of the Exchange Act Against The Individual Defendants

215. Lead Plaintiff incorporates ¶¶ 1-214 by reference.

216. The Individual Defendants acted as controlling persons of Impax within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level

positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Lead Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Lead Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

217. In particular, each of these Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

218. As set forth above, Impax, and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

219. Defendant Hsu acted as a controlling person of Impax within the meaning of Section 20(a) of the Exchange Act. By reason of his position as CEO, President and director of Impax, and his ownership of Impax stock, Hsu had the power and authority to cause Impax to

engage in the wrongful conduct complained of herein. By reason of such conduct Hsu is liable pursuant to Section 20(a) of the Exchange Act. At the end of the class period on March 4, 2013, Hsu directly owned 621,060 shares of Impax common stock, and indirectly owned over 2.3 million shares of Impax common stock via the Hsu Family trust, with another 151,213 shares of Impax common stock indirectly owned through his spouse. Hsu signed Impax's filings with the SEC including Forms 10-K and 10-Q.

220. Defendant Koch acted as a controlling person of Impax within the meaning of Section 20(a) of the Exchange Act. By reason of his position as CFO and Executive Vice President, Finance, and his ownership of Impax stock, Koch had the power and authority to cause Impax to engage in the wrongful conduct complained of herein. By reason of such conduct Koch is liable pursuant to Section 20(a) of the Exchange Act. Koch left Impax on June 29, 2012, and his most recent filing with the SEC on May 30, 2012 stated that Koch owned 142,415 shares of Impax common stock. Koch also signed Impax's filings with the SEC including Forms 10-K and 10-Q.

WHEREFORE, Lead Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action and certifying Lead Plaintiff as class representative under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Lead Plaintiff and the other Class members against all Defendants for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Lead Plaintiff hereby demands a trial by jury of all issues so triable.

Dated: September 13, 2013

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